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Research effort was directed at validating the concept of using a handheld, battery operated, cw microwave radar, operating at 2.45 GHz, for use as a heart rate monitor under chemically contaminated battlefield conditions. Verification of radar measurements under laboratory conditions was made by literature references and laboratory demonstrations. A breadboard system was designed and evaluated with relatively good results for prone, stationary patients, but erratic performance, probably caused by reflections from antenna side leakage, was observed during transport in a tracked vehicle outfitted as an ambulance.

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20. Abstract (cont'd.)

Some circuit modifications and improved shielding are recommended for Phase II prototype models.

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NONINVASIVE HEART RATE MONITOR

Final Report, Phase I

Daniel D. Mawhinney

August 1983

Supported by

U. S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Fort Detrick, Frederick, Maryland 21701

Contract No. DAMD17-83-C-3018

RCA Laboratories
Princeton, New Jersey 08540

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SUMMARY

This report describes research effort aimed at validating the concept of a Noninvasive Heart Rate Monitor (NIHRM) suitable for field use when both the person being monitored and the person using the instrument are wearing protective garments.

The principle employed by the NIHRM is the change in the phase of reflection of a weak microwave signal as it is directed towards the moving chest wall. Preparatory to the construction of a breadboard evaluation unit, tests have been conducted on (1) the preferred frequency of the interrogating signal, (2) the type of antenna providing the best compromise between size and directivity, (3) the nature of the received signal, (4) the shape of the reflected signal after detection, and (5) suitable logic and display circuitry. These tests are described in the report.

The breadboard unit is a small (1.6 cm x 0.9 cm x 0.75 cm) box having a flat antenna on one face (the face placed against the fully-clothed patient) and the digital readout on the opposite face. Although some insufficient suppression of extraneous motion was discerned during testing in an M113 tracked vehicle at Aberdeen Proving Grounds, it is nevertheless considered that the design of the various components of the instrument as well as its overall operation warrant continuation of the program, involving the final design and fabrication of 24 evaluation models. It is recommended that the fabrication and evaluation of one additional prototype unit be included in Phase II of this effort.

FOREWORD

This final report was prepared at RCA Laboratories, Princeton, New Jersey under Contract No. DAMD17-83-C-3018 for the U.S. Army Medical Research and Development Command at Fort Detrick, Frederick, Maryland. The report describes the design and development research for a Noninvasive Heart Rate Monitor (NIHRM) to be used in chemically contaminated areas where both the patient and aidman must be completely covered by protective clothing.

The work on Phase I was performed from Dec. 1, 1982 through July 31, 1983 at the RCA Laboratories Microwave Technology Center, which is directed by Dr. Fred Sterzer. The program was supervised by Markus Nowogrodzki, Head of the Microwave Subsystems Group. The design, development and evaluation work was performed by Daniel D. Mawhinney, Member of the Technical Staff, and Henry F. Milgazo, Senior Technical Associate. Guidance and support was provided by Robert W. Paglione, Member of the Technical Staff.

The author gratefully acknowledges the assistance and support of Carl Thayer, Technical Contract Monitor, especially for his counsel on potential field problems and for his cooperation and assistance in arranging, and participating in, the field tests at the Aberdeen Proving Grounds.

For the protection of human subjects, the investigators have adhered to policies of applicable Federal Law 45CFR46. (See Appendix F.)

Citations of commercial organizations and trade names in this report do not constitute an official Department of the Army endorsement or approval of the products or services of these organizations.

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I. INTRODUCTION

There is a need for a miniaturized, lightweight, portable Noninvasive Heart Rate Monitor suitable for use in chemically contaminated areas on patients wearing protective clothing. The overall objective of this program is to develop and produce a small quantity of such heart rate monitoring devices for evaluation and use under various hostile ambient field conditions.

The specific objective of Phase I was to determine the validity of the concept and design approach proposed for these prototype developmental Noninvasive Heart Rate Monitors (NIHRM).

The concept selected for this research effort employs the motion detection capability of a microwave frequency cw Doppler radar system similar to those in widespread use for traffic control, intrusion alarms, and, even, automatic door openers. A number of years ago, RCA Laboratories built and demonstrated a noncontacting microwave respiration monitor for apnea warning purposes; the presence of a signal component related to the beating of the heart was observed and recorded. Various references in the literature concern either microwave Doppler systems used for monitoring cardiac and arterial actions or other microwave measurements, such as torso attenuation or water content of the lungs, being affected by heart motion.

Observation of Doppler signal waveforms generated by cardiac action on instruments in an engineering or medical laboratory, while necessary to the conception of the basic approach, is not sufficient to validate the concept or the approach for use under the conditions and constraints of this military application. This report presents the details of experiments, measurements, and proposed designs which, it is believed, provide a sound argument for the approach as well as a positive assessment of the practicality of a microwave Doppler Noninvasive Heart Rate Monitor for use under chemically hostile battlefield conditions.

To accomplish this Phase I objective, it was necessary to examine and solve a number of specific problems and to make a number of design tradeoffs before the final design approach could be presented. Included among these problems and design choices were:

1. Selection of the monitor's specific microwave frequency, which involved a tradeoff between size and rf penetration of the protective garments and the tissue.

2. Extraction of the heart-beat-generated signal from among similar Doppler signals produced by respiration and other chest and monitor motions and vibrations.
3. Minimization of the spatial sensitivity of the monitor placement on the patient without degrading accuracy.
4. Sensitivity and dynamic range of the microwave receiver in the presence of wide variations in signal level.
5. Determination of calibration methods and self-test features to be incorporated in the monitor.
6. Consideration of microwave oscillator, signal amplifier logic, and display designs within the battery power constraints of the objective specifications.
7. Packaging for mechanical and chemical environments encountered in field use.
8. Human engineering conditions related to the handling, operation, and reading of the instrument under field conditions by an aidman wearing chemical protective clothing.
9. Reliability, availability, and maintainability capabilities consistent with similar proven medical instruments.

In addition to these tasks, although not actually required by the contract for Phase I, an advanced breadboard evaluation model was fabricated (with the concurrence of the Technical Monitor) for evaluation in an M113 tracked ambulance.

Discussions of the topics listed above are presented in the body of this report. Various laboratory measurements and tests on breadboard circuits, evaluation of remaining design problems, and performance results obtained with the advanced breadboard evaluation model clearly demonstrate the viability of the proposed approach and the desirability of proceeding with Phase II of the program -- the fabrication of 24 developmental prototype Noninvasive Heart Rate Monitors for advanced evaluation.

II. TECHNICAL DISUCSSION

A. PROGRAM OBJECTIVES

The fundamental objective of the program is to develop and fabricate a small number of Noninvasive Heart Rate Monitors for military use in high noise, chemically contaminated areas where both patient and aidman are completely covered by inviolable protective clothing. To meet this overall objective, it is necessary to design a small, lightweight, mechanically rugged, sealed, battery operated instrument that quickly displays an accurate reading of the patient's heart rate.

The objective of the Phase I research was to verify that the selected concept and the chosen design approach would lead to the fabrication of Noninvasive Heart Rate Monitors capable of meeting the functional objectives during Phase II. The purpose of this Final Report is to describe the design approach and provide sufficient related data to show that the concept and approach are valid. A more comprehensive definition of the program objectives and the scope of work is contained in the following extract from the contract:

> PHASE I
>
> The contractor shall conduct an exploratory developmental program to determine validity of the concept and approach. Essential to validation is use with chemical protective overgarments while in a high noise/vibration environment. Accurate display of heart rate is essential. The contractor shall design and develop a prototype monitoring device which will meet the following characteristics and operational requirments:
>
> a. The system, as currently envisioned, shall consist of modular electronic circuitry necessary to read the heart rate of a patient in a chemical and/or conventional field environment and to digitally display this data to the operator. The sensing elements of the system and/or the signal processing electronics shall be designed to discriminate against spurious responses caused by background noise, patient movement, and other perturbances. The sensors shall be noninvasive and shall be capable of being affixed to a patient such as not to require holding in place by the operator. The patient sign to be dealt with by this development shall be heart rate.

b. The device shall provide vital signs readout from patients inclosed in protective dress or protective patient wrap without violating the integrity of the protective covering. The protective clothing is a laminated nylon tricot knit (MIL-C-43858) covered by a 5 oz cotton twill.

c. The device must be operable by personnel wearing field protective equipment.

d. The device shall be operable in a chemically contaminated environment without becoming contaminated internally.

e. Maximum use should be made of chemical resistant materials and/or chemical agent paint for ease of decontaimation of the external surfaces of proposed equipment, component, and containers.

f. The device shall be capable of operating for six (6) hours continuously on internal rechargeable batteries.

g. The device shall be capable of providing information on conventional casualties to avoid duplication of equipment.

h. The device shall be rugged, durable, and of a compact size (i.e., the size of a package of cigarettes), lightweight, and simplistic so that a technician can move, operate, and routinely maintain the system.

i. The device shall be designed for ease of operator/organizational maintenance and require minimal repair parts support.

j. The device must accommodate storage in, and transit through, climatic categories Hot (A1) through Severe Cold (C3) inclusive, as described in AR 70-38 (1 Aug 79). The device shall be suited for use in categories Hot and Basic climatic design.

k. The device shall operate in a high noise and vibration environment, such as a helicopter or an M113 tracked ambulance.

l. Reliability, Availability and Maintainability (RAM). Commercial state-of-the-art technology shall be used to develop life expectancy, reliability, availability, and maintainability characteristics in the device. Adherence to vital signs monitoring equipment standards should help develop RAM values for this device. Minimum requirements are that RAM characteristics be consistent with commercial performance proven acceptable through use by

medical operators. AAMI standard for electronic and automated sphygmomanometers shall be used as the commercial standard.

m. The device shall be constructed of materials which will not cause safety or health hazards to patient or using personnel. All component materials shall have been declared safe for use by The Surgeon General.

n. The device shall be easily unpackaged and require little or no assembly.

o. The device shall be packed in a reusable container. Container must be dust proof, rain proof, and protect components from vibration, drop, and transit shock in accordance with MIL-STD-810c.

p. The device shall conform to portability standards expressed in MIL-STD-1472 when containerized.

The contractor shall submit a final report validating the concept and approach not later than six (6) months from the effective date of this contract. This shall constitute the end of Phase I. The government has allowed 45 days for review and approval of the Phase I Final Report.

PHASE II

1. Funding for Phase II shall be contingent upon approval of the Phase I Report by the Government. Upon initiation of Phase II, the contractor shall have six months to provide 24 Developmental Prototype Heart Rate Devices with containers and accessory items listed in Section F. Deliveries or Performance.

2. The contractor shall bear primary responsibility for the conduct of the research and shall exercise judgment towards attaining the stated research objectives within the limits of this contract's terms and conditions. Written approval of the Contracting Officer shall be obtained prior to change of the methodology or experiment, stated objectives of the research effort, or the phenomenon or phenomena under study.

B. DESIGN APPROACH

There are several types of instruments that can be used outside of medical or engineering laboratories for measuring heart beat rate. These instruments

may have sensors which detect any one of several heart-beat-produced effects, including sound, motion, pressure, IR reflectance or electrical currents which can be converted into a readable display with simple circuitry. Those based on sound, either direct or electronically-aided auscultation, are generally not useful in high noise areas and are reduced in effectiveness by protective covering. Electrical pickups are also not usable without skin contact. Motion detection by interferometer techniques using laser or other light sources and photo-plethysmography methods with LED and IR pickups are rendered completely useless by layers of opaque clothing and protective covering.

Longer wavelength electromagnetic energy in the rf region of the spectrum can penetrate most nonmetallic materials and, particularly at microwave frequencies, can be used to sense the presence, position, and movement of material boundaries that reflect even a small amount of the emitted energy. This ability to sense and process signals -- which results from comparing time, amplitude, frequency, and phase differences between transmitted and reflected signals -- is the essential element of radar technology. Continuous wave (cw) microwave radar is widely used in diverse applications such as traffic control, intrusion alarms, speed measurement, and automatic door openers. A detailed explanation of the operation and application of cw microwave radar and the related Doppler frequency shift phenomenon can be found in many radar texts and handbooks [1,2].

Basically, the operation of cw microwave radar can be understood by considering the consequence of combining, or mixing, a sample of the transmitted signal with the miniscule amount of signal reflected back from some object, commonly referred to as the target. Depending upon the phase relations between the sample and the reflected signals, the result will be usually a minute increase or decrease in the detectable signal level at this point. Except in specialized interferometer type measurement apparatus where it may be used to determine position, this fixed offset level is barely discernible and not especially useful.

If, however, the target is in motion relative to the transmitter, then the small offset level changes and a small time-varying component is added to the mixed signal. It is this alternating signal that is processed in most simple cw microwave radars.

For speedometers or traffic control radars, the frequency of the alternating signal, the Doppler frequency, is proportional to relative speed and is

processed to display miles per hour. For motion detectors, such as automatic door openers, the presence of an alternating signal is sufficient to trigger the desired response.

For measuring the periodicity of some form of regular reciprocating motion, the waveform obtained from the detected mixer output can be filtered and viewed on an oscillograph or processed and counted against a known timebase to compute revolutions per minute (RPM) or, as in the area of interest of this project, beats per minute (BPM).

Several years ago, while working on a cw microwave radar type respiration monitor for apnea detection and alarm, scientists at RCA Laboratories observed and recorded waveforms with signals that were obviously the result of motions synchronized with, and probably directly caused by, the beating of the heart. Detectable signals at the heart rate were observed on an oscillograph at distances as far as 2 meters, using an X-band (10 GHz) radar. Detailed descriptions of the cw microwave radar and the resulting waveforms were presented in the previously supplied RCA proposal for a "Noninvasive Heart Rate Monitor" [3].

There are a number of articles in the literature concerning the detection of cardiac action or related motions which substantiate the premise that cw microwave radar is a viable measurement technique. J. Lin, et al., report the use of microwaves to measure chest wall motion in response to left-ventricle activity to record apexcardiograms without the possible distortions caused by the pressure of a microphone pickup taped to the chest [4]. S. Stuchly, et al., have demonstrated the use of microwave Doppler radar to monitor the movement of arterial walls and have presented recorded waveforms obtained from viewing four major arteries from which the pulse rate could be clearly determined [5].

Others in using or evaluating cw microwave techniques for medical measurement or diagnostic purposes, such as the measurement of microwave attenuation in the human torso [6], electromagnetic wave effects on biological materials and systems [7], mapping of internal organs [8], or diagnosis of pulmonary edema [9], have reported observations of cardiac position and motion which affected their measurements.

Although it is clearly substantiated from the above examples that the heart rate can be detected using cw microwave radar in the laboratory, no evidence has been presented that such a technique, or the necessary apparatus,

can be transferred to the chemically contaminated battlefield and still continue to provide accurate information.

The major effort of Phase 1 has been directed at arriving at a design approach having this capability by performing various experiments and analyses to verify the validity of the selected concept. As part of this work, an advanced breadboard evaluation model was fabricated and tested. Although a number of construction details will be completely different and there will be other circuit design modifications made to the proposed developmental prototype models, the basic block diagram of the evaluation model (Figure 1) is representative of the proposed approach.

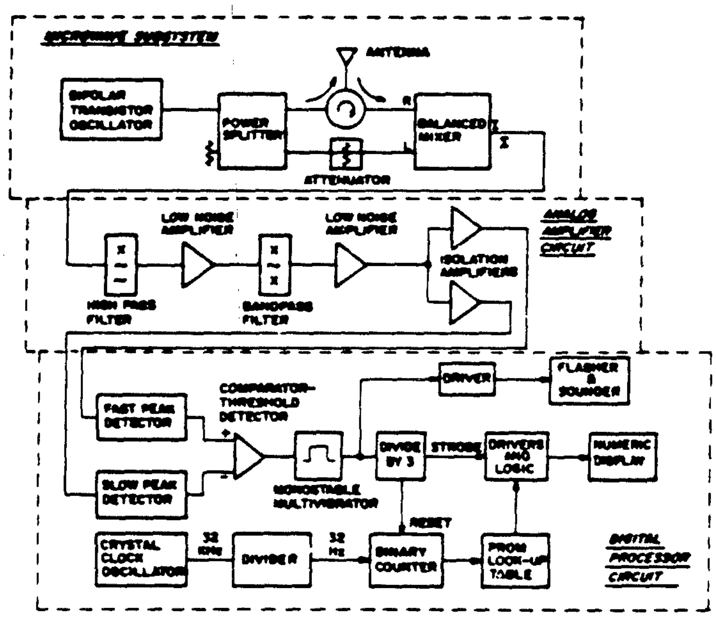

Figure 1. Noninvasive heart rate monitor block diagram.

A microwave oscillator, operating at 2450 MHz, provides the output signal for coupling to the patient through a low profile antenna structure. A sample of this oscillator output is also applied to the local oscillator input of a balanced mixer to which the reflected signal is coupled through the directional

action of a ferrite circulator. The summed output of the two diodes in the balanced mixer is amplified in a low noise, instrumentation type, operational amplifier and filtered so as to enhance the type of signal typically generated by the motions produced by cardiac action.

Following additional amplification, the signal is split and used to drive a special comparator - threshold detector which further differentiates the heart beat type waveform from those produced by respiration or slow patient movements, and which automatically corrects the threshold level to compensate in part for amplitude variations expected from different patients and positions.

The output of the threshold detector is further processed and used to strobe a reading to the LED display and to reset a binary counter which has been counting clock pulses derived from a crystal controlled reference. The count is converted to beats per minute -- using a look-up table memory element and displayed. An LED flasher and piezoelectric sounder provide visual and audible marks at each beat to help in operating the monitor.

The problems requiring solution to transfer the proposed approach from the laboratory to the field concern patient movement and respiration, surrounding motion, high ambient noise levels, battery power and size constraints, positional sensitivity and patient variability, chemical contamination, and ruggedness. More details of the proposed design and the means of solving these problems is presented in the following sections describing specific design features.

In summary form, our proposed approaches to these problems are:

<u>Patient motion</u> - The NIHRM will be held against the patient firmly -- but not oppressively -- by the aidman or held in place by a supplied adhesive foam pad or strap. It is relative motion that the radar detects; by reducing the sensitivity of the system to other body motion as much as practical, absolute patient movement will have little effect unless it is very pronounced and sudden.

<u>Respiration</u> -- The signal output from normal respiration is more sinusoidal in nature than that of the pulse-like heart beat. Filtering and simple processing can separate the signals and exclude respiration from the heart rate determination. Unusual respiration -- irregularity, gasping, apnea recovery, etc. -- will probably affect the accuracy of an unaveraged short term reading, but the monitor would read, and might alert the aidman by, the irregularity of the rate.

Surrounding motion - The design of our breadboard evaluation unit did not take surrounding motion into sufficient consideration. The presumed solution was simply that contact of the antenna with the patient (through the protective coverings) would prevent anything else from being "seen" by the radar. This proved to be wrong because the antenna is separated from the patient's lossy skin and tissue by the protective clothing and by a thickness of plastic covering the antenna face. There was considerable sideward leakage from the antenna-patient interface as well as some leakage from the monitor itself which was not adequately shielded.

Proposed corrections include encasing the NIHRM in a metal housing with a frame of microwave absorptive material to attenuate leakage. This is a technique we have used previously to reduce sidelobes on a locomotive radar speed sensor with good results. Pads of microwave absorptive material will also be provided to cover the monitor, except for the display, in areas where extreme external relative motion will be encountered, such as during transport. Changes in the processor, discussed elsewhere, will also limit the blocking effect caused by the large signals which can be generated by motion inside a metal vehicle.

High noise levels -- Although sound does not affect the cw microwave radar or the accuracy of the reading, vibrations associated with high levels of sound and noise will cause relative motion between the NIHRM and other objects. The improved shielding and leakage suppression discussed above will isolate the monitor adequately in most foreseeable instances.

Battery power -- An analysis of the battery requirements are included in a later section. A rechargeable battery pack of reasonable size and weight can meet the operational requirement of the application.

Positional sensitivity and patient variability -- Positional sensitivity, which results in a wide range of signal characteristics and level, was of considerable concern, and the attention directed to it resulted in the design of a special threshold detector that automatically adapts to the input level and to a decision to use a balanced mixer rather than the simple self-mixing technique usually employed in simple cw microwave radars.

Chemical contamination and ruggedness -- The developmental prototype models will be compact units built into metal cases and sealed so that vapors will not normally get inside the cases, but reasonable and prudent procedures must be followed after any exposure to dangerous chemical agents. The NIHRM will need nonmetallic plastic windows for the display and for the microwave antenna. These will be gasket sealed to the metal case. If the gasket area is damaged, the possibility of chemical agents being inside the case must be presumed. Decontamination procedures within the storage temperature range limits will not damage the units with intact seals. The plastic window will be a clear, extremely rugged polycarbonate generally unaffected by greases, oils and acids. Further guidance in the area of material selection will be solicited for the prototype model design prior to fabrication.

C. SIGNAL INVESTIGATIONS

Considerable effort was directed at determining the optimum microwave frequency for the NIHRM. The properties of radio frequency waves, particulary at microwave frequencies, are such that the penetration of muscle, skin, and tissues decreases as the frequency rises. Specific data given by C. Johnson and A. Guy [7] show that for frequencies from 0.1 to 10 GHz the penetration varies from 6.7 to 0.34 cm for tissue with high water content and from 6.1 to 3.4 cm with low water content. For the best operation of the NIHRM, there should be sufficient penetration to reach the heart itself, since pressure against the chest through the coverings will suppress movement of the chest wall relative to the monitor; however, there must not be so much transmission that significant microwave energy completely penetrates the torso, allowing external motions to produce extraneous signals.

A second factor in frequency selection is the size of the antenna or coupling structure. For comparable performance, as the frequency is increased, the antenna dimensions can be reduced. Size reductions can be made by using high dielectric materials for the antenna, but for a first order tradeoff, it is desirable to operate at a higher frequency for antenna size minimization. In general, deep penetration by the microwave energy and reduction in size of the monitor are contradictory objectives when selecting the operating frequency.

To provide experimental results to assist in the selection of the operating frequency, a series of microstrip patch antennas were designed and fabricated for operation at frequencies from 2 to 12 GHz, and tests were conducted at five frequencies in this range. Figure 2 shows this group of nominally flat antennas. Input impedance measurements were made on each of these antennas,

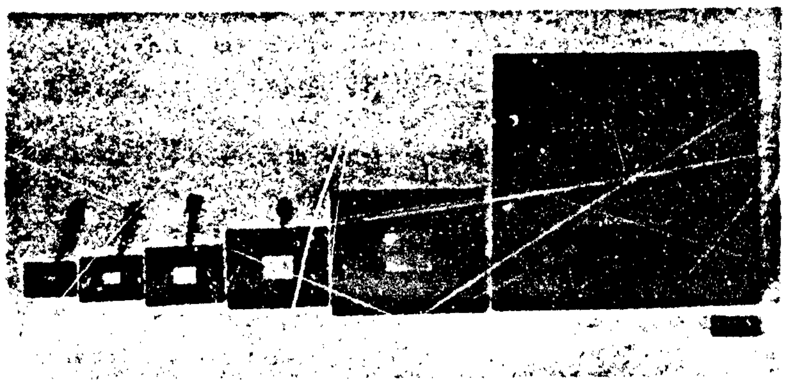

Figure 2. Flat, printed patch antennas operating at different microwave frequencies.

using the RCA Microwave Technology Center Phase Locked Automatic Network Analyzer (PLANA) with the antennas looking into a free space absorber and then pressed against the operator's chest. Those antennas designed for the lower frequencies -- 2 through 8 GHz -- were generally well matched to the chest near the design frequency; the 10 and 12 GHz antennas were less well matched, but usable for evaluation tests. In each case, a test arrangement was assembled using various oscillators, mixers and circulators connected as shown in Figure 3. Some of these components and the antennas can be seen in the photograph of the test station (Figure 4) used for the sensitivity tests. Sensitivity variation resulted from the use of different mixers and probably accounts for the poor returns measured at 4 GHz where the mixer was at the end of its rated band. In all other cases, the results were of the same general magnitude.

A description of the tests and the recorded waveforms are presented in Appendix E.

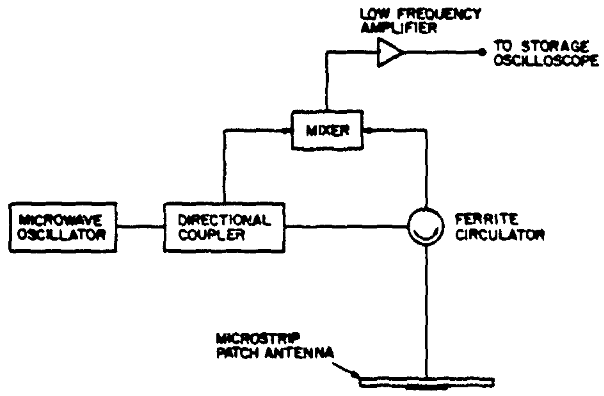

Figure 3. Block diagram of equipment used for sensitivity vs frequency tests.

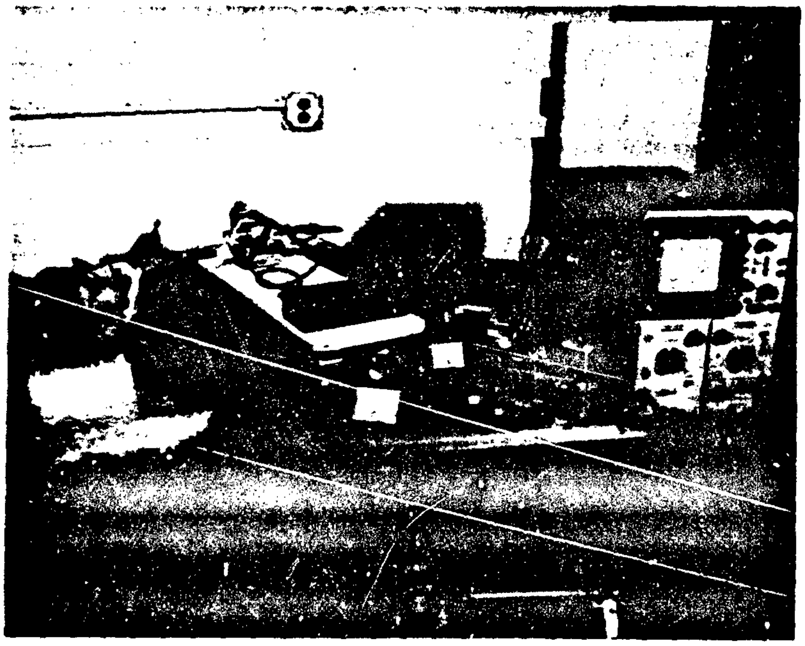

Figure 4. Experimental setup for preliminary measurements of signal reflections from chest wall.

The conclusions drawn from these measurements include:

1. Large amplitude variations could be expected from the radar mixer as the antenna was moved away from the subject's chest.
2. The higher frequencies, which have shorter wavelengths, showed more positional sensitivity than the lower frequencies.
3. Pressing the antenna against the chest wall reduced the signal, indicating that most of the detected signal was from chest wall motion.
4. The waveform was complex probably because it was the resultant of -- at least -- composite movement of the chest wall, the precordium, blood flow and heart motion.
5. The waveforms appeared to be somewhat less complex when the antenna was pressed against the chest. Respiration signals were also reduced with close contact.

The major conclusion was that for contact monitoring -- which is necessary where we expect patient or carrier movement -- the lower frequency will provide a stronger signal, but not so much stronger that higher frequencies cannot be used. The relatively good results we had at 2150 MHz led us to select an operating frequency of 2450 MHz -- an FCC allocated and widely used frequency for medical and industrial applications.

D. ANTENNA DESIGN

The purpose of the antenna is to couple the transmitter output into the patient's torso in the vicinity of the heart and to receive reflections related to the heart movement. Since the use of microwave energy on humans for diagnostics or treatment requires an efficient coupling structure, especially at high power levels, considerable work has been directed to the design of microwave applicators [10,11,12,13].

Often materials with high dielectric coefficients are used to reduce the size of the applicator and to better match the impedance of the human body. To provide information for the applicator design, measurements have been reported on the transmission and reflection characteristics of muscle, tissue and skin under various conditions over the radio and microwave frequency spectrum [7].

Normal microwave antenna design assumes radiation into free space with or without special boundary conditions. The NIHRM antenna falls somewhere between

an applicator and an antenna since it will be spaced away from direct chest contact by an unknown number of layers of clothing, probably wrinkled and bunched so as to contain air gaps, and a protective plastic window as a part of the sealed case of the monitor. Physically, the antenna should have a flat profile and be lightweight.

Considering the good performance of the 2150 MHz microstrip patch antenna during the signal investigation tests, the decision was made to use a similar design, but with a higher dielectric material and designed to operate at 2450 MHz. The earlier test models had been made using a flexible copperclad PFTE-based microwave circuit board with a 2.3 dielectric constant, but the breadboard evaluation model antenna was made from a similar microwave circuit board having a composite substrate material resulting in a dielectric constant of approximately 10.

All of the microstrip patch antennas were designed using a simple program based on design formulas given by Bahl and Bhartia [14]. The program and the runoffs which give the patch dimensions for various frequencies are presented in Appendix B.

Using the PLANA test facility, the input impedance characteristics of the high dielectric microstrip patch antenna were measured with the antenna face pressed against the chest wall of the subject through various combinations of the supplied military clothing. Test data printouts and a plot of the input VSWR (Voltage Standing Wave Ratio) were obtained for all of the test conditions. VSWR is one means of expressing impedance match which relates the incident and reflected signals. A VSWR of 1.0 represents a perfect match (no reflection) and higher values indicate a poorer match. For example, a VSWR of 3.0 means that approximately 25% of the incident power is reflected. It does not necessarily follow that the remaining 75% is coupled into the subject since there are antenna and leakage losses to be considered, but, in general, the lower the VSWR the better the coupling. An example of the test results is shown in Figure 5. The best match is at about 2500 MHz when the antenna is held over the left pocket flap of the chemical protective coat worn over the combat coat and the other clothing of the test subject. It was intended to do some tuning to improve the match after the antenna was mounted in the evaluation model housing to further reduce the VSWR at the operating frequency.

Appendix C consists of a number of similar VSWR plots for the various combinations of clothing and other conditions. There is some variation but not

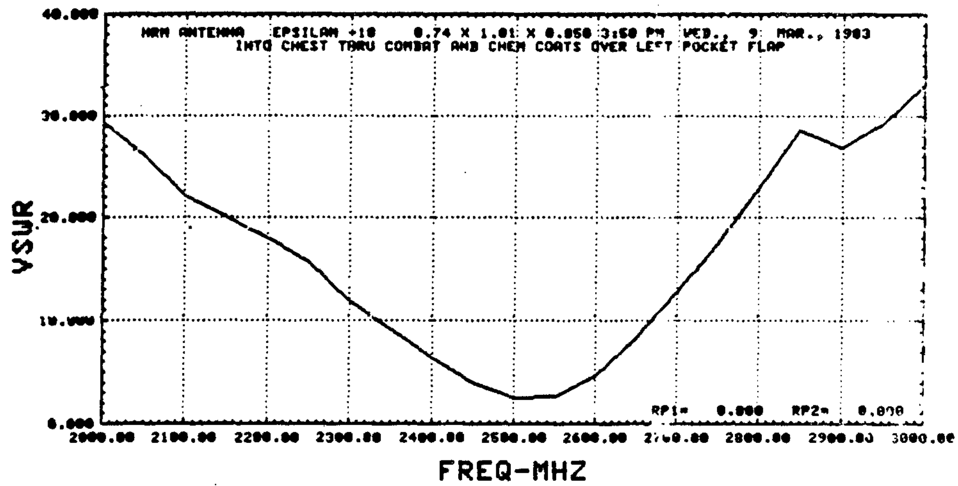

Figure 5. VSWR plot, beam from patch antenna directed into chest through combat and chemical coats over left pocket flap.

an unreasonable amount, except for direct skin contact where the match is very poor. This condition will not occur in practice because a plastic window will be used to cover the antenna and seal the monitor housing.

Figure 6 shows a bistatic antenna structure using two microstrip patches instead of the single patch actually used. It would be advantageous if a bistatic antenna, which uses one patch for transmitting and one for receiving, could be used to eliminate the bulky ferrite circulator. Tests made with this antenna were not positive, probably because the separation is too great for the close proximity of the target. Further testing with the antennas angled inward towards each other is probably warranted and will be done prior to the design finalization in Phase II.

In summary, the antenna structure will be either a single or dual microstrip patch antenna made on a high dielectric substrate. The overall physical size will be in the order of 100 mm long x 60 mm wide x 2 mm thick. The radiating, or coupling, patch will be about 18 x 25 mm -- an area of about 450 sq mm. To remain within the safe electromagnetic wave energy limit of 10 mW/sq cm, the radiated power should be kept below 45 mW.

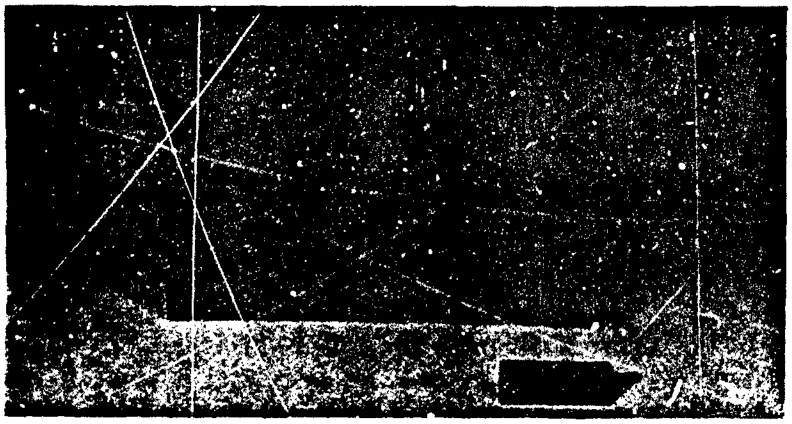

Figure 6. Microstrip patch antenna, bistatic version.

It is considered that this antenna design is well suited to the application because of its small size, flat profile, lightweight, and tolerance of variations of the protective garments.

E. MICROWAVE SUBSYSTEM

The microwave subsystem consists of an oscillator, a ferrite, a circulator, and a balanced mixer which, respectively, generate the microwave signal, separate the output and received signals, and extract the Doppler signal from the microwave frequency components. The oscillator and mixer have been especially designed for use in the NIHRM. The circulator is a purchased component.

At 2450 MHz, many bipolar and field effect devices could be used for the oscillator device. The Hewlett-Packard HXTR-4101 was selected since it is particularly characterized for oscillator use at frequencies as high as 4.3 GHz. A microstrip configuration using the microwave circuit board material having a dielectric constant of 10 was selected because of its relatively small size. The circuit consists of several transmission line elements connected to the transistor which function as the resonant circuit (base), feedback (emitter), and output matching (collector). Lumped element chokes and capacitors provide the isolation and bypassing for the dc connections to the batteries. Bias is provided by a large series emitter resistor connected to a negative voltage since the base is dc grounded and the collector supply voltage is in the order of +7.2 vdc.

The oscillator circuit was first built using the microwave board material with the 2.3 dielectric constant and then scaled to the higher dielectric material. Figure 7 shows both breadboard designs, which have comparable performance, and provides a direct size comparison. The heavy metal plate is for the test facility only and not included in the final design.

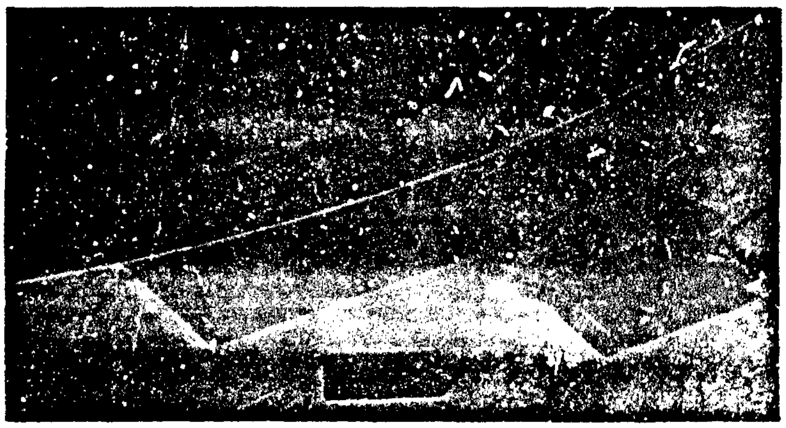

Figure 7. Oscillator breadboard circuits.

Measured separate from the antenna and mixer, the oscillator provides an output power of 4 to 24 mW at approximately 2450 MHz with the current set between 6 and 15 mA. The oscillator will be somewhat decoupled from the load for stabilization in actual use and the output split so that about one-half of the oscillator output will provide local oscillator drive for the mixer diodes. Assuming conservatively that the antenna mismatch and loss will be low enough to permit transmission of 75% of the split oscillator power to be radiated, about 24 mW of oscillator power will result in a radiated power level of 9 mW, which is 20% of the maximum safe limit of 45 mW determined in the antenna design section. The oscillator current can be held to 15 mA maximum to assure that the maximum safe level will never be exceeded nor even approached.

Tests were made to determine if adding a dielectric resonator to stabilize the frequency was warranted. Since performance without the resonator was

satisfactory and the dielectric resonators (Figure 8) proved to be quite bulky, they will not be incorporated into the oscillator design.

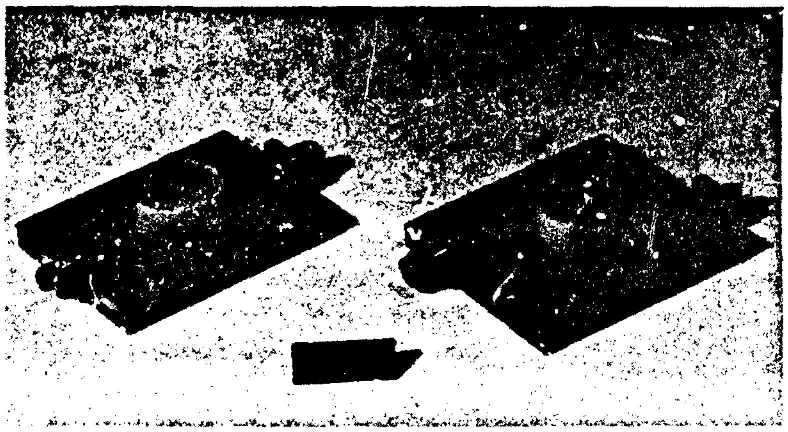

Figure 8. Dielectric resonators.

Operation under input conditions of about 7.5 vdc and 15 mA is well under the manufacturer recommended operating conditions of 15 vdc and 30 mA [15].

It is proposed that the above described oscillator design be included in the developmental prototype models. The design employs readily available microwave components; the transistor operates well within its maximum ratings; efficiency, including bias resistor and decoupling losses, is reasonable; and the physical size is quite small and compatible with the remainder of the microwave circuit.

The balanced mixer configuration was chosen to reduce positional dependency, which was found troublesome when simple mixing techniques were used. In the balanced mixer, the phase relationships of the two diodes are offset by about 90 degrees so that both outputs cannot go through a null phase or a low sensitivity phase at the same relative position of the transmitter and target.

A simple ring hybrid was designed for the mixer and was also used as a power splitter. The test hybrid ring is shown in Figure 9 mounted on a test fixture. Spacings are arranged so that an input at either of the two in-line

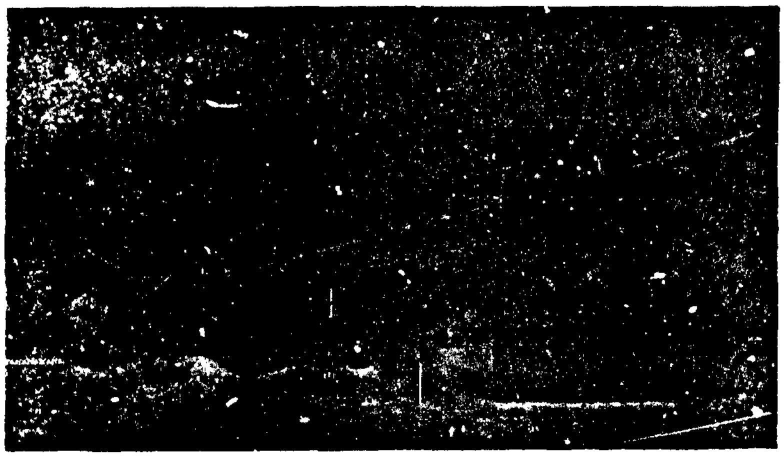

Figure 9. Ring hybrid on test fixture.

connectors will be evenly divided between the opposite port and the closer off-line port, and the farther off-line port will be isolated. The phase shifts required for balanced mixer operation are provided by this circuit which was also built on the material board with the higher dielectric constant.

A breadboard of the balanced mixer was fabricated using a pair of encapsulated, commercially available Schottky-diodes recommended for mixer applications as high as 10 GHz. To determine the matching circuit required, a diode was mounted on the test fixture (Figure 10) and measured on PLANA. The results were transferred to a microwave CAD program, COSMS, and a simple transmission line matching section designed, using the same dielectric constant material as for the ring.

To evaluate the balanced mixer and determine that it would reduce the positional dependency of the system, a simple test arrangement was put together in which the radar system -- constructed of the breadboard oscillator, antenna and mixer -- was positioned on a moveable jackstand above the rim of a rotating dielectric wheel with a small metal strip at one spot. This simulated a reciprocating target, and the output of both mixers was observed at different positions. At no point did the sum of the mixer output drop to zero although individual nulls were apparent. The details of these observations are contained in Appendix D.

Figure 10. Mixer diode on test fixture.

The combined microwave system is shown in Figure 11. Built on a single circuit board, the oscillator is at the upper left corner in a cross-like configuration with the collector output line -- to which a tuning stub was later added -- connected to the hybrid ring which divides the power between the in-line output and the first off-line output (at 60 degrees CCW) which supplies local oscillator power to the mixer diodes via the second hybrid splitter after being attenuated in the small chip resistor network between the two rings. The output of the upper ring and the input to the lower ring are connected through the circuit board to the ferrite circulator which connects to the antenna by a cable not shown in the photograph.

Since the overall performance of the microwave subsystem has been excellent and should to be relatively inexpensive to produce and reliable in operation, it is proposed to use this arrangement in the developmental prototype models. As mentioned, the bulkiness of the circulator is a concern, but if the dual antenna can be used, this circuit is fully compatible since the input/output lines were designed to connect to either arrangement.

F. DIGITAL PROCESSOR CIRCUIT

The digital processor converts the amplified heart beat waveform to a numeric display of the rate in beats per minute (BPM). For the evaluation

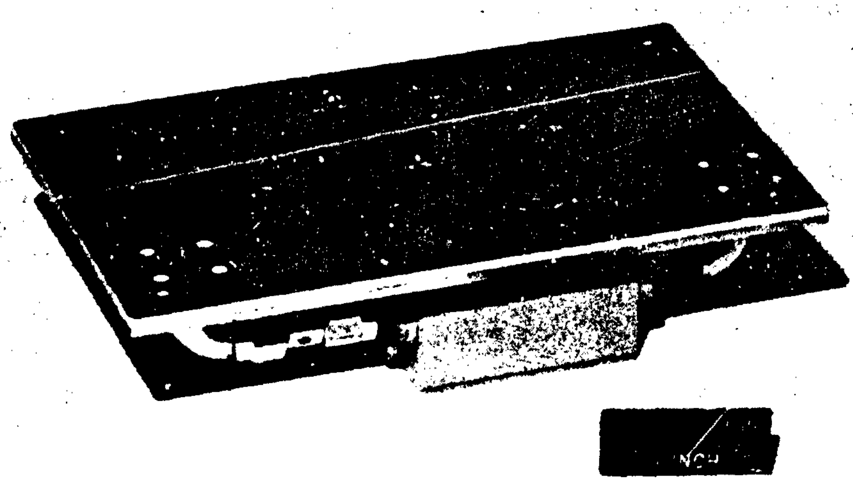

Figure 11. Combined microwave system.

model, after a simple circuit which displayed BPM from 15 second interval counts was built and determined to be too slow, a somewhat more involved circuit was used which measured the interval between three successive beats and used a look-up PROM to determine the BPM rate for the LED display.

This method provides a reading in about 2 to 4 seconds for heart beat rates from 90 to 45 BPM and is updated at the same rate. Although the processor circuit that we suggest be used for the prototype developmental units has some important changes, the evaluation model circuit (Figure 12) will be described first and then the proposed changes discussed.

The output of the signal amplifier is a pair of nominally equal signals from two unity gain operational amplifiers intended to isolate the sensitive analog amplifier circuits from the pulsating digital processor. These two signals are modified by separate peak detector networks with different charge and discharge rates and the resulting signals applied to the differential inputs of a comparator operational amplifier.

The reason for using two channels with different effective time constants is to separate slower and more sinusoidal signals produced by respiration and

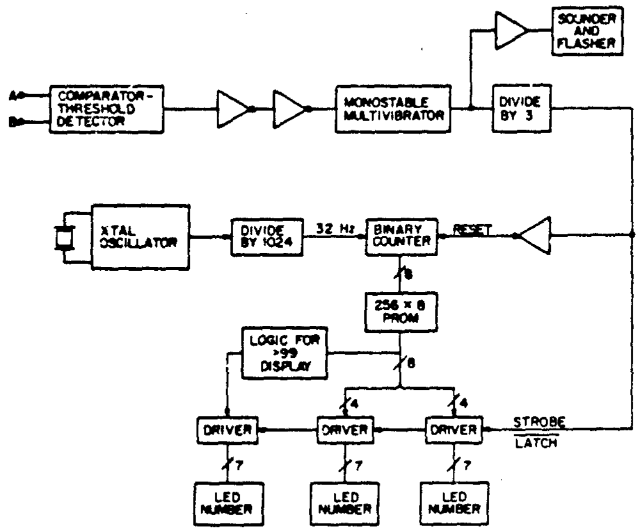

Figure 12. Digital processor block diagram.

subject movement from the pulse type of signal produced by the action of the heart. The reason for the peak detector or peak holding circuit is to provide an automatic threshold level control which adapts itself to the average level of the incoming signal.

With reference to Figure 13, the operation of the comparator - threshold detector is:

Channel A signal input develops the threshold level for the comparator through the peak storage network consisting of R1, D1, C1, and R3, where R3 is much larger than R1. The corresponding network of Channel B consists of R2, D2, C2, and R3, but the values differ in that C2 is smaller than C1 by a factor of 10, providing a smaller charging and discharging time for the B signal. R1 and R2 are equal, but R4 is less than R3 so that the A signal, the threshold level, is attenuated less and overrides the B signal for slowly changing signals.

Since the peak voltage developed by the A channel signal is stored in C3 and allowed to discharge much more slowly than the B channel signal, the threshold level tends to follow the peak input signal, but with enough decay in the normal interval between heart beats to allow the next fast pulse through as a beat. The action of the differential amplifier is to produce a positive output when the signal overrides the floating threshold.

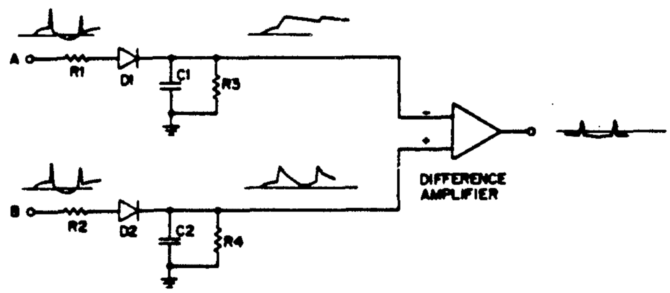

Figure 13. Comparator - threshold detector operation.

This comparator - threshold detector circuit differentiates quite well between the heart beat and respiration signals, but it has one shortcoming which should be corrected in the prototype models. Very large signals from sudden subject or monitor movements tend to drive the threshold level far above that produced by normal signals, blocking one or more subsequent beats. In a counting system measuring the interval for three heart beats to occur, missing one beat will cause the monitor to read low by a significant amount, 45 instead of 60 BPM, for instance. (The comparator - threshold detector proposed for the prototype developmental units will have two additional features -- (1) signal levels significantly greater than the average level will be recognized by a two-level comparator and not considered as valid heart beat signals, and (2) the threshold level will be averaged over a longer period and not be allowed to increase significantly because of sporadic large amplitude signals.)

The output of the comparator - threshold detector is sharpened in a pair of CMOS inverters and used to trigger a monostable multivibrator to produce a standard pulse of about 200 ms. This pulse length limits the rate measurement to 1/200 ms or 300 BPM, which is beyond the readout limit but, at the same time, should prevent double counts from heartbeat waveforms with multiple peaks, such as that shown in Figure 14.

The standard pulse is divided by three and used to reset the clock counter and strobe the display output. The clock signal used is 32 Hz, derived from a 32,768 Hz crystal. The relation between the number of clock pulses counted in

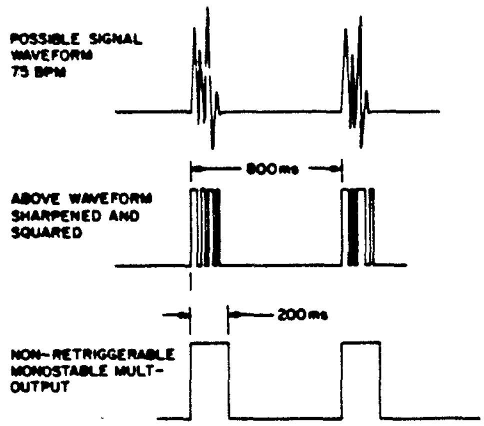

Figure 14. Reduction of spurious counts by use of standard length output pulse.

the interval datermined by the spacing of heart beats has an inverse relation to the BPM quantity. The relation can be calculated from the expression:

$$BPM = 60*K*Fc/N$$

where K = The heart beat pulse divisor

N = The number of counts in K beats

Fc= The counter input clock frequency

A simple computer program (Appendix A) was written and run to show the relation between BPM and N for several values of selected clock rate and heart beat divisors. As stated, a divisor of 3 and a clock rate of 32 Hz were selected for the evaluation model because BPM values from 23 to 199 would produce counts of 250 to 28, which fall within an 8-bit data capability and have tolerable resolutions varying from +/- 1 BPM at 23 to +/- 5 BPM at 199.

The remainder of the digital processor consists of a PROM into which is loaded the N to BPM look-up table obtained from the program runoff (shown in part in Appendix A) and the LED display and associated drivers. In addition to the BPM display, an LED flasher and a piezoelectric sounder driven from the standard multivibrator pulse were included in the evaluation unit. Both the visual and audible indications are intended to match the heart beat on a one for one basis and provide help in positioning the monitor for a regular and

meaningful count as well as indicating the regularity of the heart beat without the need for monitoring the display.

For the prototype models, the same general type of circuit is suggested with some basic modifications. To reduce the effect of a missing beat or extraneous input pulse, the output should be averaged over more than 3 pulses. To do this without requiring a longer wait for the first reading and updates, it is suggested that the count data be stored in 8-bit parallel shift registers and added together with logic circuitry to eliminate any unreasonable counts and adjust the average accordingly. A lower accuracy reading would be available after just 2 or 3 beats but the accuracy would automatically improve as the averaging time increased. Depending upon the room available for shift register chips, from 6 to 10 interval counts would be added to obtain the long term average.

G. DC POWER REQUIREMENTS

The NIHRM is required to operate from rechargeable batteries for at least 6 hours before recharging. Of the four basic sections of the NIHRM, namely the microwave oscillator, the signal amplifier, the digital processor, and the LED display, only the oscillator and the display consume significant power and they have been used to determine the battery requirements.

The bipolar transistor, grounded-base oscillator designed for the evaluation model operates over a moderately wide voltage range with the current set by an emitter resistor in series with a single 3.6 vdc lithium battery. With two more of the same type of lithium batteries used for the collector supply (7.2 vdc), the current was usually set between 10 and 15 mA. Battery current drain was much greater for the three 7-segment LED numerical indicators used in the evaluation unit. Operated from a centertap grounded pair of the same 3.6 vdc lithium batteries, the total driver and display current rose as high as 250 mA, depending upon the number of segments driven.

For the prototype model NIHRM, it is essential that size and weight be considered in the battery selection process as well as duration of operation between recharging cycles. Of the several types of rechargeable batteries available, the selection of sealed nickel cadmium cells appears to be most consistent with the reliability, availability, and maintainability (RAM) requirements of the program as well as with the power needs of the NIHRM. Nickel-cadmium batteries are in widespread commercial use in diverse tools and

instruments, operate in any position, have almost constant output voltage over life at differing discharge rates, function over a wide range of ambient temperatures (typically -40 to +60 degrees C), and can be run through hundreds of charge/discharge cycles with little degradation.

Cylindrical cells are widely used and are relatively inexpensive and available. Typical ratings for the commonly used AAA (10.5 mm D X 44.5 mm L) and AA (14.5 mm D X 50.0 mm L) sizes are capacities of 180 and 500 mA, respectively, with corresponding weights of 10 and 24 grams. Using the nominal C/10 discharge rate for computation, the output voltage of these cells would be expected to drop from 1.2 to 1.0 vdc in 10 hours at discharge currents of 18 and 50 mA, respectively. Approximately 14 hours would be required to recharge a fully discharged cell at this same C/10 rate although more rapid charging rates can be tolerated if temperature limits are controlled.

For the prototype NIHRM, it is recommended that a battery pack consisting of 7 AAA and 4 AA cells wired as shown in Figure 15 be used. For the oscillator, the same +7.2 vdc will be available at a C/10 discharge rate of 18 mA, but the emitter bias battery will be changed to -1.2 vdc, reducing the unnecessarily large voltage drop in the emitter resistor. The collector and emitter current drains, which are about the same and no more than 15 mA, will be supplied by the 7 AAA cells comfortably for the required 6 hours of operation.

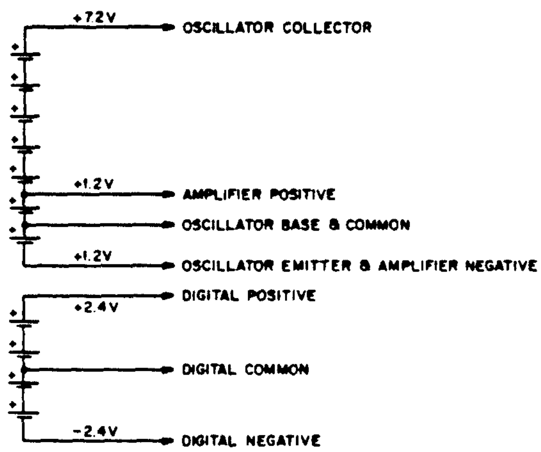

Figure 15. Battery voltage configuration.

To reduce the heavy current drain of the LED display, a higher efficiency solid state mumeric indicator, such as the HP 5082-7433, will be employed in

the prototype NIHRM. Although characterized as having excellent readability at 0.25 mA per segment -- which would require a current total of 4.0 mA for the worst-case 16 segments to display "188" -- the numeric indicators will be run at a significantly greater average current, tentatively 2.5 mA per segment, for better daylight readability. Under the same maximum display current load of a "188" reading, the total current would be 40 mA; however, since the number of segments activated at any instant will usually be less than 16, the total average current is estimated at 30 mA.

Current requirements for the remaining digital circuitry, LED flasher, and a piezoelectric sounder will be no more than 5 mA. The resulting total display and digital processing circuit current drain is estimated at 35 mA, which is comfortably below the C/10 discharge rate of 50 mA for the AA nickel cadmium cell and which should provide for more than 10 hours of operation under ideal conditions until the output voltage drops from 1.2 to 1.0 vdc for each cell.

Since there is some cell degradation after each charge/recharge cycle, leakage loss, and efficiency reduction at ambient temperature extremes, some margin beyond the 6 hour limit is required. A tentative layout of the battery pack as a part of the digital processor/display sub-module is shown in Figure 16. It is estimated that the overall dimensions of the sub-module will be in the order of 140 mm X 90 mm X 32 mm with a probable battery weight of 160 grams. It is considered that the size and weight of this battery configuration is a reasonable tradeoff for operational margin.

H. CALIBRATOR

During the testing of various components and assemblies, it was inconvenient to use a subject at all times. At first, a slowly driven dielectric rod rotating in and out of the antenna field was used, but the displacement was magnitudes greater than the heart beat movement. Later, we used piezoelectric sounders as the moving target. These devices, which are widely used as beepers or alarms, emit an audible tone at a specific frequency. The ones we used operate at low dc voltages and produce tones at about 3000 Hz. There is only a miniscule movement of the diaphragm -- less motion than the heart undergoes during beating.

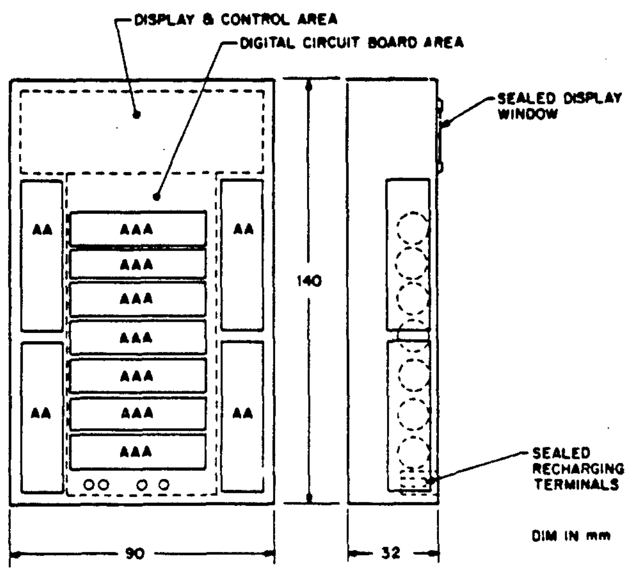

Figure 16. Tentative battery pack layout.

By driving the piezoelectric sounder with 0.1 sec. pulses at an adjustable rate comparable to the heart rate, an output signal waveform much like one from monitoring the heart was obtained. The sounder was used extensively to evaluate and optimize the operation of various circuits during the later stages of the program.

Additionally, the use of the piezoelectric sounder as a calibrator was tested and will be incorporated in the developmental prototype design, as it was in the breadboard evaluation model. A crystal controlled oscillator -- using the same crystal and type of circuitry as is used in many digital watches -- driving a CMOS divider and multivibrator was designed to provide 0.1 sec pulses at 0.5 sec intervals for the piezoelectric sounder. This is equivalent to a heart rate of 120 BPM.

The sounder and circuit will be built into the carrying case and can be used for checking the accuracy of the NIHRM quickly and conveniently. An on-off switch will be provided and the sound will be quite muted by the confines of the case.

The calibrator will draw very little current and will operate from a two-cell rechargeable battery which will be automatically charged along with the monitor battery pack.

This simple calibrator is recommended for use because of its inherent accuracy, minimal cost, compactness, and compliance with the program objectives.

I. BREADBOARD EVALUATION UNIT

The evaluation unit, which was assembled from the separate breadboard circuits described earlier in this report, is physically quite different from the proposed developmental prototype models, but it is a relatively good electronic and microwave equivalent. Therefore, the evaluations made related to the basic performance can be reasonably extrapolated to the proposed models. Those electronic deficiencies which remain, such as the lack of averaging and blocking by large signals, will be corrected.

The leakage problem -- the reason for erratic and unusable performance in the tracked vehicle -- must be solved mainly by the physical design which will be completely different than that of the breadboard model.

The breadboard evaluation model (Figure 17) was assembled within two standard bakelite instrument boxes mounted back to back, and is about 160 mm x 90 mm x 75 mm in size -- a volume almost twice that which the developmental prototype units will have. The microwave signal is coupled through the plastic wall -- bakelite is not a particularly good microwave material -- with the antenna located about opposite the display window. Three LED numerical indicators are mounted behind the window alongside of which is a simple LED that flashes for each detected heartbeat. In synchronism with the flash, a piezoelectric sounder inside the box is pulsed and can be heard for a short distance. The on-off switch, which must be recessed and sealed in the final model, is also shown.

The breadboard evaluation model was transportad in the carrying case shown in Figure 18. To the left of the monitor is the area under which the calibrator is mounted. To check the operation of the NIHRM, it may be placed on top of this surface, as shown in Figure 19, and it should read 120 BPM. With front and back covers of the breadboard evaluation model removed, the microwave system and analog amplifier can be seen in Figure 20 while the digital processor and display are shown in Figure 21.

Figure 17. Breadboard evaluation unit.

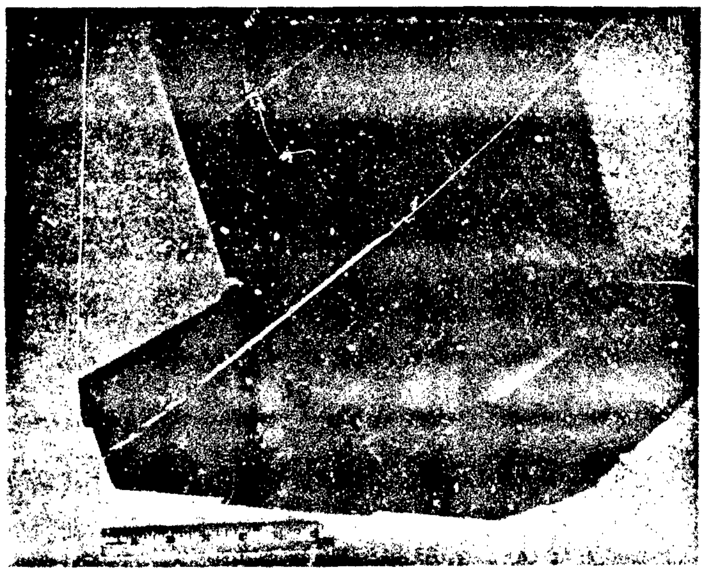

Figure 18. Breadboard evaluation unit in carrying case.

Figure 19. Breadboard evaluation unit on top of calibrator reading 120 BPM.

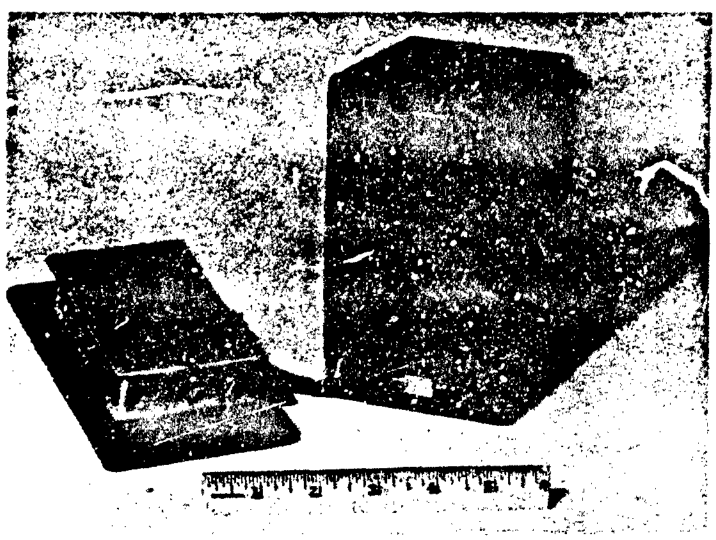

Figure 20. Microwave system and analog amplifier from breadboard evaluation model.

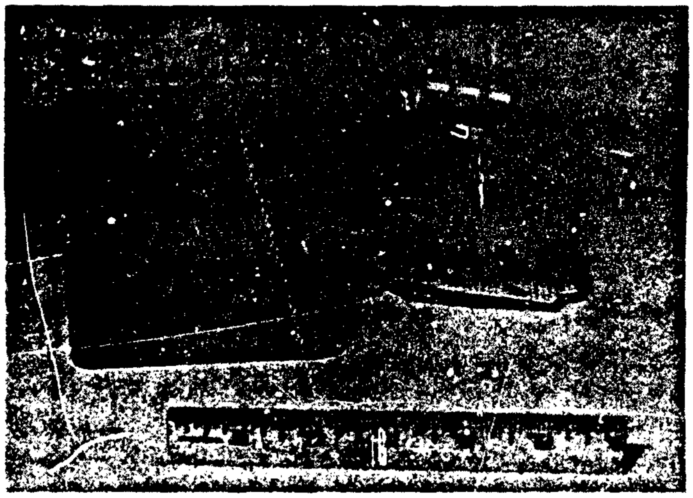

Figure 21. Digital processor and display from breadboard evaluation model.

Basically, the unit is easy to use. One turns it and the calibrator on, waits a few seconds for the internal transients to settle, and places it on the calibrator to verify that it is functioning. Then one picks it up and holds it against the patient's chest, firmly but not oppresively, in the vicinity of the heart. It is helpful to watch the LED flasher and, if possible, listen to the sounder to see if a regular beat is being obtained. If so, a new reading should appear after every third beat. Moving the monitor will cause extraneous readings so it is best to move it in increments and wait a few seconds at each new position if it is necessary to search for a stronger (more regular) signal.

The developmental prototype models will be about the same in terms of ease of operation. Instructions will be printed in the carrying case.

J. DEMONSTRATION OF BREADBOARD EVALUATION MODEL

To test the advanced breadboard evaluation model under field conditions, the Technical Monitor arranged for a test run in an M113 tracked vehicle which was rigged for a litter. The testing was performed on 22 July 1983 at Aberdeen Proving Grounds.

The following results were obtained:

1. With the subject (patient) lying in the litter while it was stationary on the floor of the garage, accurate and consistent readings were obtained. The NIHRM breadboard model, which is quite oversized, was held in place with two-sided cushioned tape.

2. With the subject lying in the litter while mounted in the M113, reasonably consistent and probably accurate readings were obtained about 80% of the time with the motor idling and the vehicle not moving.

3. In the same position, with the vehicle in motion over smooth or rough roads, the readings were too erratic to determine the heart rate or even make a life/death determination.

It is believed, as has been mentioned earlier in this report, the erratic readings were mainly produced by strong reflections -- of signals leaking from the antenna side -- from the metal walls of the vehicle. It will be necessary to improve the shielding and reduce the antenna microwave leakage before fabrication of the developmental prototype models.

The basic operation of the breadboard model under stationary conditions was quite promising. Although there are several distinct improvements to be made to the follow-on models, the breadboard model has demonstrated that the following major objectives can be met with certainty:

1. A handheld cw microwave radar can detect the heart beat rate.
2. Normal respiration is not a major concern.
3. Battery power is sufficient to drive the entire monitor.
4. The radar can be fully contained with no exposed radiating or coupling structures.
5. The heart beat can be discerned through the protective clothing.
6. An accurate calibrator can be included.
7. With proper mixer design, position of placement affects the signal strength but is not so critical as to be a major problem as originally suspected.

III. DEVELOPMENTAL PROTOTYPE MODELS

The basic concept, design approach, and proposed microwave and processor circuits of the developmental prototype models have been described in various sections of this report. Where these have differed from the breadboard evaluation model, the reasons and proposed changes have been described. Therefore, in this section, only a summary of the proposed design is given.

The proposed developmental prototype models will use the cw microwave radar approach to detect the heart motion. A bipolar transistor oscillator operating at 2450 MHz and biased to limit the antenna output power to less than 9 mW will be fabricated on a microwave circuit board along with a ring hybrid balanced mixer. Either a single printed microstrip patch antenna and a ferrite circulator or, less likely, a bistatic printed antenna without a circulator will be used to separate transmitted and received signals.

An analog circuit comprised of two amplifier stages with filtering to optimize the response to the heart beat waveform and a pair of output isolation amplifiers will be built on a conventional printed circuit board. The two output signals will be processed by a comparator-threshold detector to further select heartbeat type signals and automatically compensate for signal amplitude variations. A modification will be made to prevent large extraneous signals from blocking the proper counting response by using a dual-level comparator. Pulses from the comparator will be used to flash an LED and a sound beeper, but mainly to reset a crystal clock counter and strobe readings into the display. A count averaging shift register will be added to lessen the effect of occasional bad counts. An LED display behind a filter and a transparent window will provide the required readout.

The unit will be encased and sealed. The case will be metal, probably anodized aluminum, with transparent plastic windows over the display and the antenna patch. Gaskets will be used to seal the windows. The unit will be about 140 mm x 90 mm x 50 mm and the weight, about 750 gms.

The carrying case will be similar to that shown in Figure 22. It will be metal and will hold the monitor in a recessed section under which will be the calibrator and the recharging circuits. Provisions for recharging from ac or dc sources will be provided.

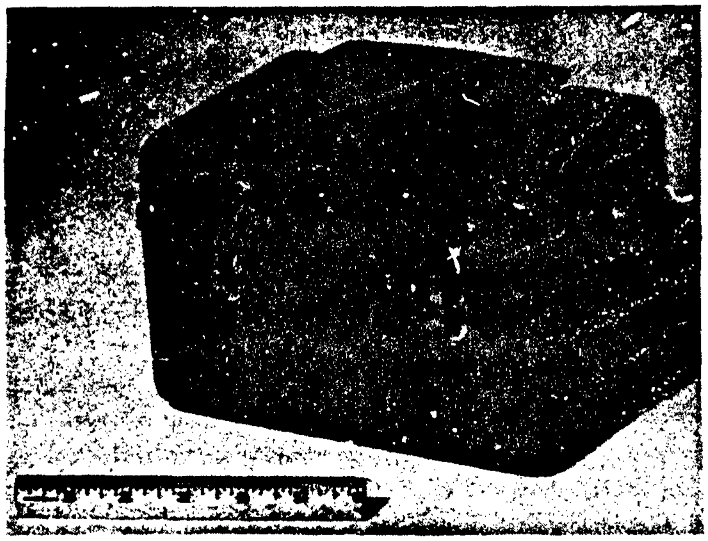

Figure 22. Commercial version of proposed carrying case.

IV. CONCLUSIONS

The background material, circuit descriptions, measurement data, and general comments provided in this report have been directed at presenting sufficient information to permit a judgment to be made of the proposed approach as a valid concept for a battlefield Noninvasive Heart Rate Monitor. The proposed approach is a small, handheld, battery operated, cw microwave radar that senses the movements associated with cardiac action through layers of protective clothing and displays the heart rate directly in beats per minute.

From this information and a general impression derived from performing the tests and using the breadboard evaluation model, RCA Laboratories has concluded that the basic proposed design approach is valid and reasonable. Deficiencies were found during the program and most have been corrected. Remaining problems are significant and must be resolved. However, promising solutions have been proposed.

From the presented evaluation and design data and the projected developmental prototype model performance, RCA Laboratories believes that the following conclusions are essentially valid answers to the contract objectives of Phase I:

a. A modular electronic assembly capable of detecting and measuring heart beat in chemically contaminated field conditions can be designed and built to the required standards.

b. The use of cw microwave radar makes it feasible to measure the heart rate through chemical protective coverings and clothing.

c. The equipment will be simple to use and can be operated by personnel wearing protective clothing. The only controls are on-off switches for the monitor and the calibrator.

d. The device can be completely sealed and, unless physically damaged, should not become internally contaminated.

e. External surfaces will be treated metal or small windows of rugged transparent polycarbonate plastic sealed with recessed gaskets. The on-off switch will be recessed and sealed and there will be two sealed feed-throughs for charging.

The carrying case will also be sealed in the section which contains the calibrator and recharger. Obvious care must be taken in opening the case after use in a contaminated enviroment.

f. Calculations and current measurements indicate that the monitor will operate for more than 6 hours before recharging.

g. The NIHRM will function as well, if not better, under conventional casualty situations as when used with victims in protective clothing since it is not critically dependent upon the protective clothing.

h. The proposed device will be simple, rugged and easy to use.

i. Repair and parts support details have not been adequately analyzed, but the nonmicrowave circuitry will be of a basic printed circuit nature with less than 100 reasonably standard and available components. The microwave circuitry should be quite reliable and even repairable with specialized test equipment.

j. Environmental testing has not been done but all components will have the required temperature range capabilities.

k. Operation in high noise and vibration areas has not been proven. It is believed that the shielding proposed for the developmental prototype models will provide this capability sufficiently to ascertain existence of a vital sign and a display of the average heart rate with occasional errors from extreme movements.

l. Reliability, Availability and Maintainability details have not been adequately detailed. Additional work will be done to quantify these items. Generally, however, the proposed device will be comparable to similar commercial devices but more rugged.

m. Material lists will be provided for safety and health analysis but no problem is expected from the inert substances which will be used.

n. Unpacking will be simple, requiring only unlatching and opening the cover of the carrying case.

o. The container will conform to the environmental and ruggedness requirements.

p. The device will meet the portability requirements when containerized.

V. RECOMMENDATIONS

Based on the conclusions presented in Section IV, it is recommended that fabrication of the developmental prototype models be authorized as Phase II of the Noninvasive Heart Rate Monitor Program.

It is further recommended that additional time be allocated in Phase II to allow for the fabrication and evaluation of one prototype model prior to design finalization. This model is expected to perform in the M113 tracked vehicle environment, but verification would be desirable and could be obtained if the time devoted to Phase II of the program were extended by 60 days to cover fabrication of the verification model.

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APPENDICES

APPENDIX A

CALCULATION OF HEART RATE FROM INTERVAL COUNTS

This appendix presents the computer program and runoff used to compute the prom look-up table to convert clock counts over heart beat intervals to beats per minute for the BCD display. The clock rate and number of heart beats over which the measurements are made are variables which may be selected to provide different resolutions.

```
FTN77
      PROGRAM BEATS
C     <830726.1356>
C     HEART RATE VS COUNT OF CLOCK PULSES
C
C  FC=CLOCK FREQUENCY IN HZ
C  BPM=HEART RATE IN BEATS PER MINUTE
C  K=HEART RATE PULSE INPUT DIVISOR (TO AVERAGE OVER SEVERAL [illegible]
C  N=NUMBER OF COUNTS
      INTEGER BPM,N,K,FC
      WRITE(1,'("TYPE IN CLOCK FREQUENCY IN Hz")')
      READ (1,*)FC
      WRITE(1,'("K IS THE HEART BEAT RATE DIVISOR    ")')
      WRITE (1,'("  COUNTS          BEATS PER MINUTE")')
      WRITE (1,'("    N       K=1      K=2      K=3      K=4  ")')
  100 FORMAT (3X,I3,4(4X,I4))
      N=1
      DO WHILE (N.LT.256)
         BPM1=1*FC*60/N
         BPM2=2*FC*60/N
         BPM3=3*FC*60/N
         BPM4=4*FC*60/N
         WRITE(1,100) N,BPM1,BPM2,BPM3,BPM4
         N=N+1
      END DO
      STOP
      END
      END$
```

:BEATS
TYPE IN CLOCK FREQUENCY IN Hz
32
K IS THE HEART BEAT RATE DIVISOR

COUNTS N	BEATS PER MINUTE K=1	K=2	K=3	K=4
1	1920	3840	5760	7680
2	960	1920	2880	3840
3	540	1280	1920	2560
4	480	960	1440	1920
5	384	768	1152	1536
6	320	640	960	1280
7	274	548	822	1097
8	240	480	720	960
9	213	426	540	853
10	192	384	576	768
11	174	349	523	698
12	160	320	480	640
13	147	295	443	590
14	137	274	411	548
15	128	256	384	512
16	120	240	360	480
17	112	225	338	451
18	106	213	320	426
19	101	202	303	404
20	96	192	288	384
21	91	182	274	365
22	87	174	261	349
23	83	166	250	333
24	80	160	240	320
25	76	153	230	307
26	73	147	221	295
27	71	142	213	284
28	68	137	205	274
29	66	132	198	264
30	64	128	192	256
31	61	123	185	247
32	60	120	180	240

COUNTS N	BEATS PER MINUTE K=1	K=2	K=3	K=4
33	58	116	174	232
34	56	113	169	225
35	54	109	164	219
36	53	106	160	213
37	51	103	155	207
38	50	101	151	202
39	49	98	147	196
40	48	96	144	192
41	46	93	140	187
42	45	91	137	182
43	44	89	133	178
44	43	87	130	174
45	42	85	128	170
46	41	83	125	166
47	40	81	122	163
48	40	80	120	160
49	39	78	117	156
50	38	76	115	153
51	37	75	112	150
52	36	73	110	147
53	36	72	108	144
54	35	71	106	142
55	34	69	104	139
56	34	68	102	137
57	33	67	101	134
58	33	66	99	132
59	32	65	97	130
60	32	64	96	128
61	31	62	94	125
62	30	61	92	123
63	30	60	91	121
64	30	60	90	120
65	29	59	88	118
66	29	58	87	116
67	28	57	85	114
68	28	56	84	112
69	27	55	83	111
70	27	54	82	109
71	27	54	81	108
72	26	53	80	106
73	26	52	78	105
74	25	51	77	103
75	25	51	76	102
76	25	50	75	101
77	24	49	74	99
78	24	49	73	98
79	24	48	72	97

COUNTS N	BEATS PER MINUTE K=1	K=2	K=3	K=4
80	24	48	72	96
81	23	47	71	94
82	23	46	70	93
83	23	46	69	92
84	22	45	68	91
85	22	45	67	90
86	22	44	66	89
87	22	44	66	88
88	21	43	65	87
89	21	43	64	86
90	21	42	64	85
91	21	42	63	84
92	20	41	62	83
93	20	41	61	82
94	20	40	61	81
95	20	40	60	80
96	20	40	60	80
97	19	39	59	79
98	19	39	58	78
99	19	38	58	77
100	19	38	57	76
101	19	38	57	76
102	18	37	56	75
103	18	37	55	74
104	18	36	55	73
105	18	36	54	73
106	18	36	54	72
107	17	35	53	71
108	17	35	53	71
109	17	35	52	70
110	17	34	52	69
111	17	34	51	69
112	17	34	51	68
113	16	33	50	67
114	16	33	50	67
115	16	33	50	66
116	16	33	49	66
117	16	32	49	65
118	16	32	48	65
119	16	32	48	64
120	16	32	48	64
121	15	31	47	63
122	15	31	47	62
123	15	31	46	62
124	15	30	46	61
125	15	30	46	61
126	15	30	45	60
127	15	30	45	60
128	15	30	45	60
129	14	29	44	59

COUNTS	BEATS PER MINUTE			
N	K=1	K=2	K=3	K=4
130	14	29	44	59
131	14	29	43	58
132	14	29	43	58
133	14	28	43	57
134	14	28	42	57
135	14	28	42	56
136	14	28	42	56
137	14	28	42	56
138	13	27	41	55
139	13	27	41	55
140	13	27	41	54
141	13	27	40	54
142	13	27	40	54
143	13	26	40	53
144	13	26	40	53
145	13	26	39	52
146	13	26	39	52
147	13	26	39	52
148	12	25	38	51
149	12	25	38	51
150	12	25	38	51
151	12	25	38	50
152	12	25	37	50
153	12	25	37	50
154	12	24	37	49
155	12	24	37	49
156	12	24	36	49
157	12	24	36	48
158	12	24	36	48
159	12	24	36	48
160	12	24	36	48
161	11	23	35	47
162	11	23	35	47
163	11	23	35	47
164	11	23	35	46
165	11	23	34	46
166	11	23	34	46
167	11	22	34	45
168	11	22	34	45
169	11	22	34	45
170	11	22	33	45
171	11	22	33	44
172	11	22	33	44
173	11	22	33	44
174	11	22	33	44
175	10	21	32	43
176	10	21	32	43
177	10	21	32	43
178	10	21	32	43
179	10	21	32	42

COUNTS N	BEATS PER MINUTE K=1	K=2	K=3	K=4
180	10	21	32	42
181	10	21	31	42
182	10	21	31	42
183	10	20	31	41
184	10	20	31	41
185	10	20	31	41
186	10	20	30	41
187	10	20	30	41
188	10	20	30	40
189	10	20	30	40
190	10	20	30	40
191	10	20	30	40
192	10	20	30	40
193	9	19	29	39
194	9	19	29	39
195	9	19	29	39
196	9	19	29	39
197	9	19	29	38
198	9	19	29	38
199	9	19	28	38
200	9	19	28	38
201	9	19	28	38
202	9	19	28	38
203	9	18	28	37
204	9	18	28	37
205	9	18	29	37
206	9	18	27	37
207	9	18	27	37
208	9	18	27	36
209	9	18	27	36
210	9	18	27	36
211	9	18	27	35
212	9	18	27	35
213	9	18	27	36
214	8	17	26	35
215	8	17	26	35
216	8	17	26	35
217	8	17	25	35
218	8	17	26	35
219	8	17	26	35

COUNTS N	BEATS PER MINUTE K=1	K=2	K=3	K=4
220	8	17	26	34
221	8	17	26	34
222	8	17	25	34
223	8	17	25	34
224	8	17	25	34
225	8	17	25	34
226	8	16	25	33
227	8	16	25	33
228	8	16	25	33
229	8	16	25	33
230	8	16	25	33
231	8	16	24	33
232	8	16	24	33
233	8	16	24	32
234	8	16	24	32
235	8	16	24	32
236	8	16	24	32
237	8	16	24	32
238	8	16	24	32
239	8	16	24	32
240	8	16	24	32
241	7	15	23	31
242	7	15	23	31
243	7	15	23	31
244	7	15	23	31
245	7	15	23	31
246	7	15	23	31
247	7	15	23	31
248	7	15	23	30
249	7	15	23	30
250	7	15	23	30
251	7	15	22	30
252	7	15	22	30
253	7	15	22	30
254	7	15	22	30
255	7	15	22	30

APPENDIX B

MICROSTRIP PATCH ANTENNA CALCULATIONS

This appendix presents the computer program for calculating the dimensions of microstrip patch antennas and the runoffs for two different micrwave substrate materials.

```
:RU,PATAN
   TYPE IN SUBSTRATE DIELECTRIC CONSTANT, THICKNESS
10.0,0.127
   TYPE IN START, STOP, INCREMENT FREQUENCIES IN GHz
2.0,3.0,0.1
      FREQ.    WIDTH     LENGTH
      (GHZ)     (IN)      (IN)
       2.0      1.26       .93
       2.1      1.20       .89
       2.2      1.14       .84
       2.3      1.09       .81
       2.4      1.05       .77
       2.5      1.01       .74
       2.6       .97       .71
       2.7       .93       .69
       2.8       .90       .66
       2.9       .87       .64
       3.0       .84       .62
```

```
:RU,PATAN
   TYPE IN SUBSTRATE DIELECTRIC CONSTANT, THICKNESS
2.32,0.318
   TYPE IN START, STOP, INCREMENT FREQUENCIES IN GHz
1.0,12.0,1.0
      FREQ.    WIDTH     LENGTH
      (GHZ)     (IN)      (IN)
       1.0      4.58      3.82
       2.0      2.29      1.87
       3.0      1.53      1.22
       4.0      1.15       .89
       5.0       .92       .70
       6.0       .76       .56
       7.0       .65       .47
       8.0       .57       .40
       9.0       .51       .34
      10.0       .46       .30
      11.0       .42       .26
      12.0       .38       .23
:
```

```
LI.&PATAN
&PATAN T=00004 IS ON CR00004 USING 00006 BLKS R=0000

FTN77
      PROGRAM PATANT
C MICROSTRIP PATCH ANTENNA DESIGN CALCULATION
C FROM "MICROSTRIP ANTENNAS", BAHL AND BHARTIA, AERTECH HOUSE
C PAGE 57; EQUATIONS 2.66 AND 2.67 AND OTHERS REFERENCED
C
C FILENAME IS DDMPAT....USUALLY CHANGE TO &PATANT FOR RTE-6 COMPIL
C
      REAL W,WIN(20),C,FREQ,F(20),ER,EE,L,LIN(20),DELTAL,H
      REAL FSTART,FSTOP,FINCR
      WRITE(1,100)
  100 FORMAT (3X,'TYPE IN SUBSTRATE DIELECTRIC CONSTANT, THICKNESS
      READ (1,*) ER,H
      WRITE(1,200)
  200 FORMAT (3X,'TYPE IN START, STOP, INCREMENT FREQUENCIES IN GH
      READ (1,*) FSTART,FSTOP,FINCR
      FREQ=FSTART-FINCR
      I=0
      C=3.0E10
      WRITE (1,400)
      WRITE (1,500)
  400 FORMAT(5X,'FREQ.',4X,'WIDTH',5X,'LENGTH')
  500 FORMAT(5X,'(GHZ)',4X,' (IN)',5X,' (IN)')
      DO WHILE (FREQ.LT.FSTOP)
         FREQ=FREQ+FINCR
         I=I+1
         FREQ=FREQ*1.0E09
      W=(C/(2.*FREQ))*((ER+1.)/2.)**(-.5)
      EE=((ER+1.)/2.)+(((ER-1.)/2.)*(1.+(12.*H/W))**(-.5))
      DELTAL=((0.412*H)*(EE+0.3)*((W/H)+0.264))
      DELTAL=DELTAL/((EE-0.258)*((W/H)+0.8))
      L=((C/(2.*FREQ*(EE**.5)))-2.*DELTAL)
         FREQ=FREQ/1.0E09
         W=W/2.54
         L=L/2.54
         WRITE (1,300) FREQ,W,L
      END DO
      STOP
  300 FORMAT(5X,F4.1,5X,F5.2,5X,F5.2)
      END
      END$
```

APPENDIX C

MONITOR VSWR PLOTS

This appendix presents the VSWR plots of the Noninvasive Heart Rate Monitor's high dielectric microstrip patch antenna under various conditions and clothing configurations.

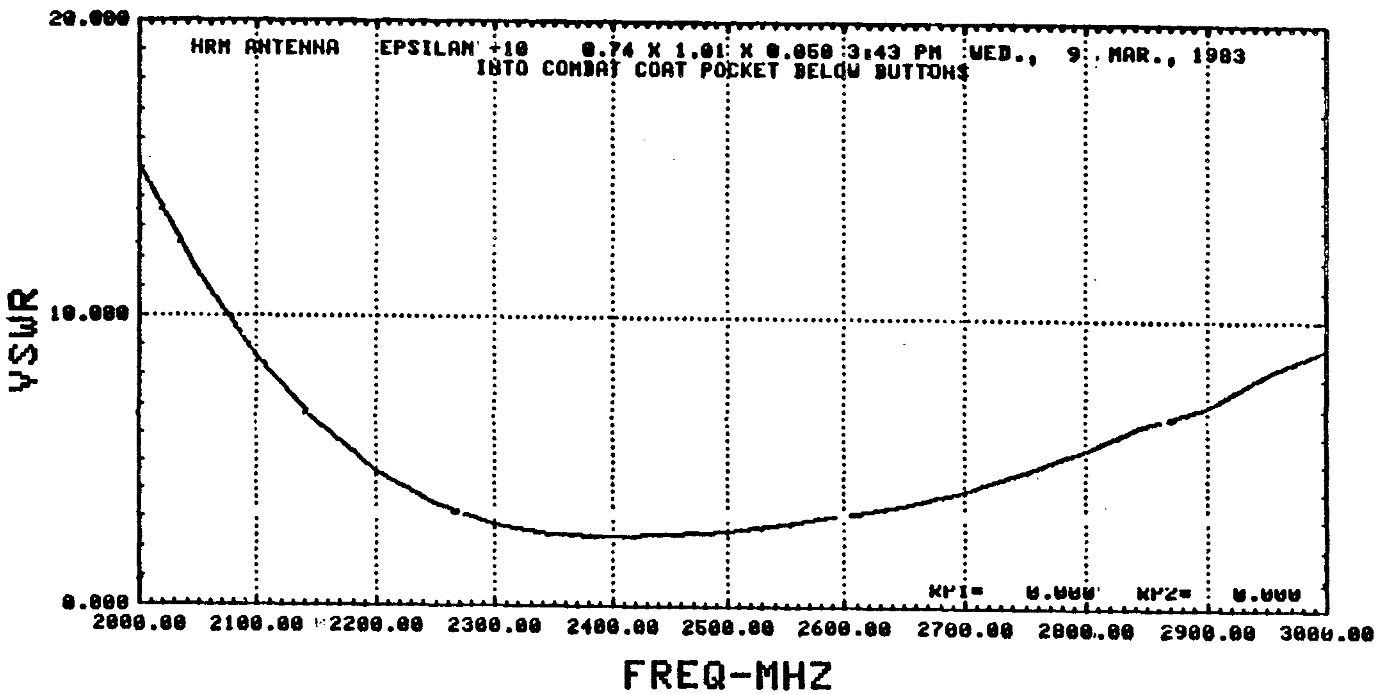


Figure C-1. VSWR plot, beam from patch antenna directed into combat coat pocket below buttons.

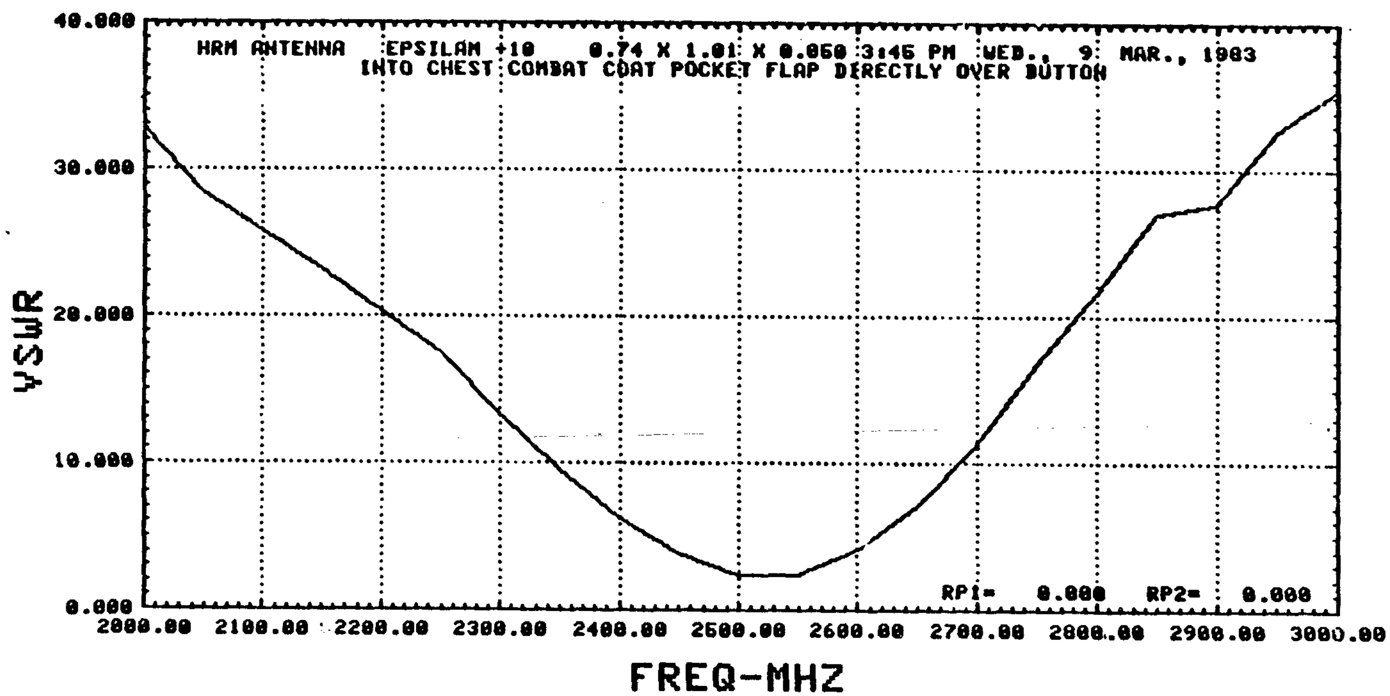


Figure C-2. VSWR plot, beam from patch antenna directed into chest combat coat pocket flap directly over button.

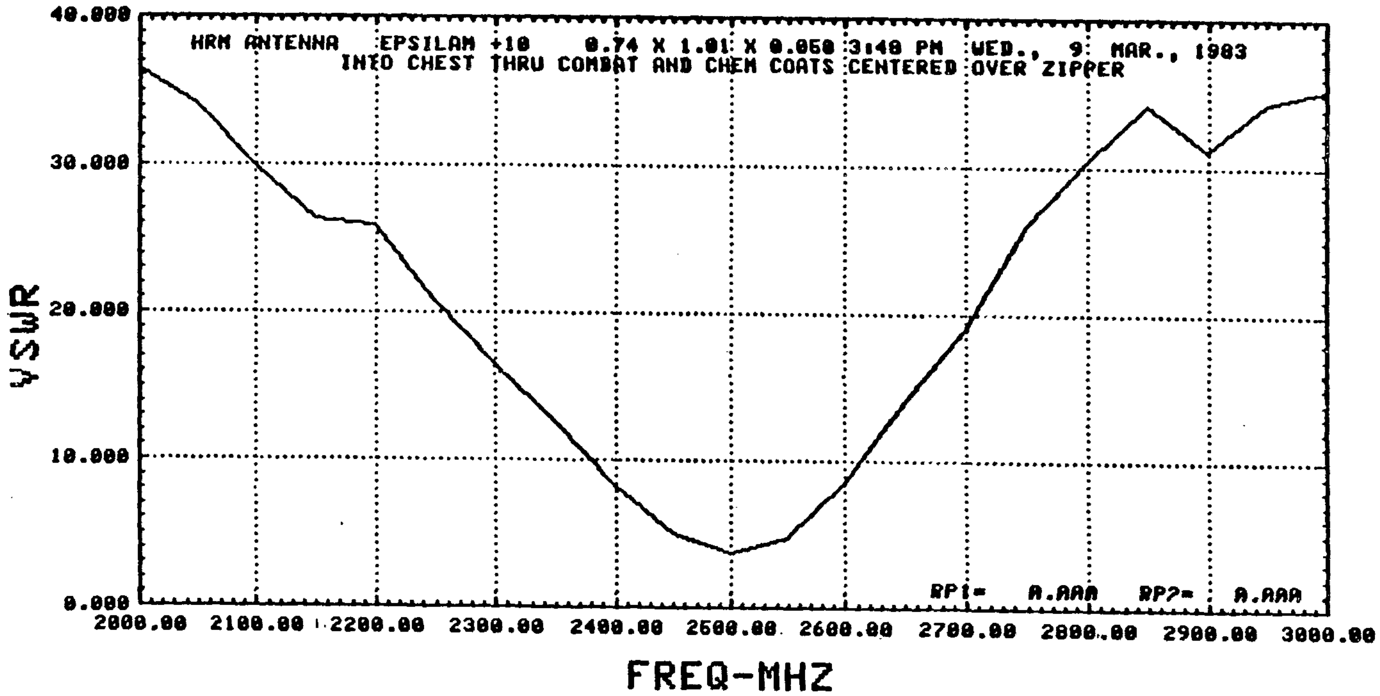


Figure C-3. VSWR plot, beam from patch antenna directed into chest through combat and chemical coats centered over sipper.

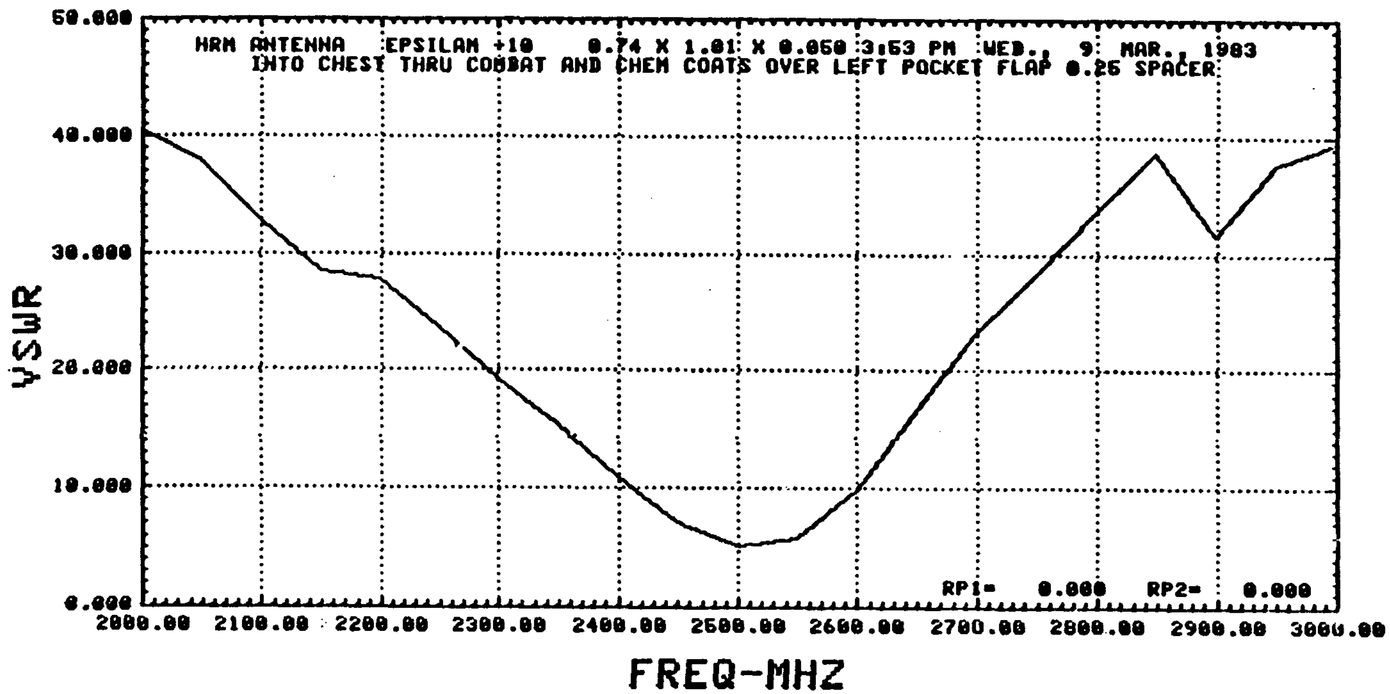


Figure C-4. VSWR plot, beam from patch antenna directed into chest through combat and chem coats over left pocket flap.

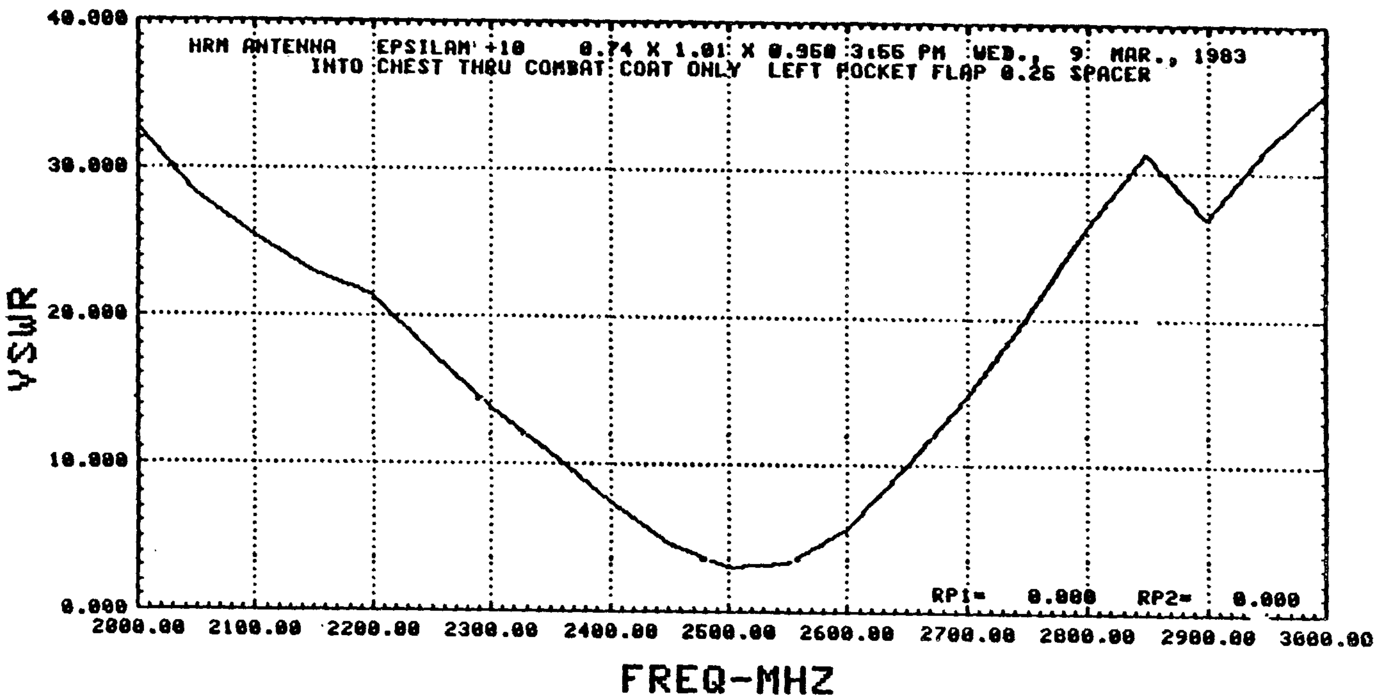


Figure C-5. VSWR plot, beam from patch antenna directed into chest through combat coat only, left pocket flap, 0.25 spacer.

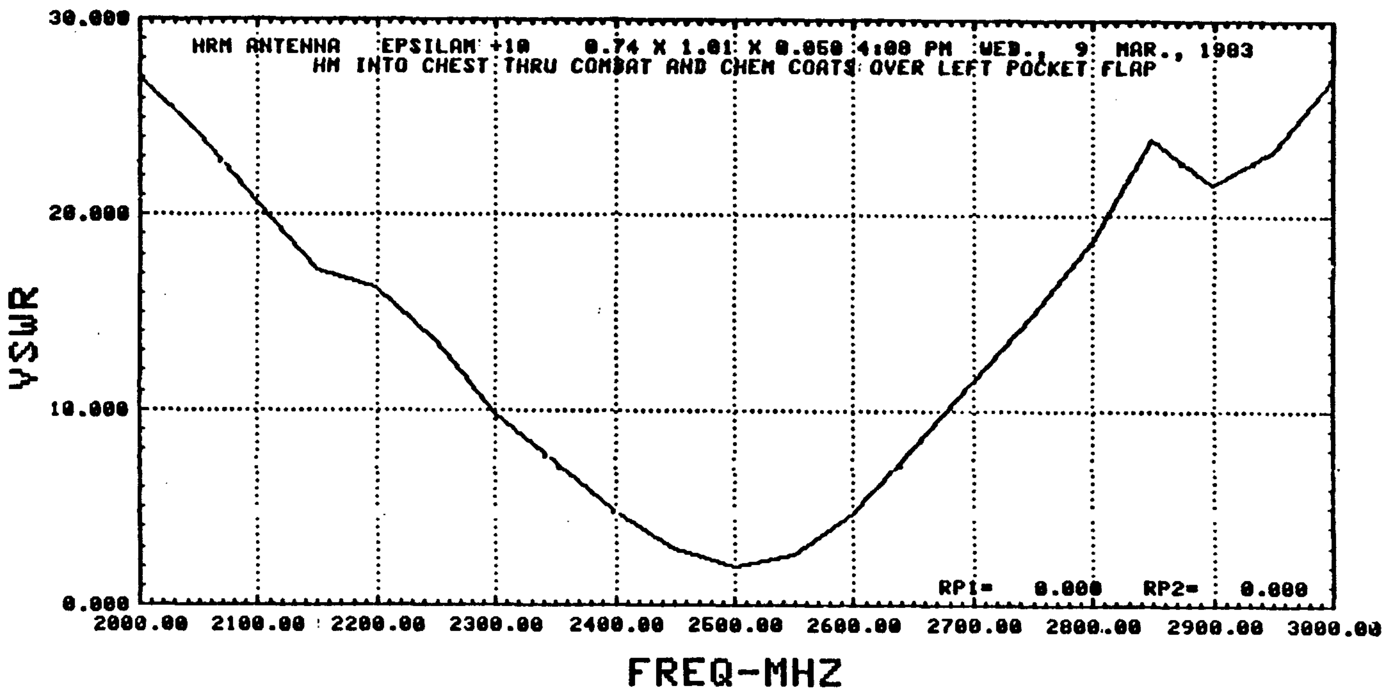


Figure C-6. VSWR plot, beam from patch antenna directed into chest through combat and chemical coats over left pocket flap.

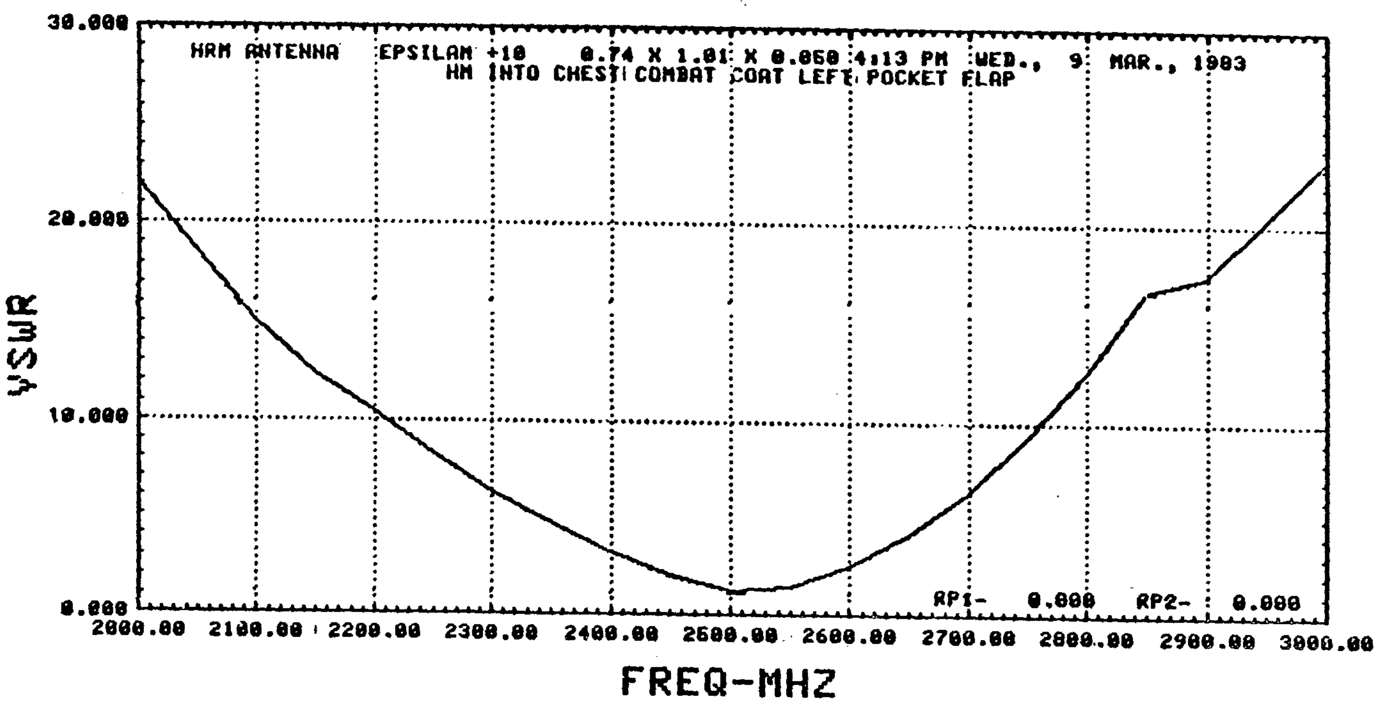


Figure C-7. VSWR plot, beam from patch antenna directed into chest through combat coat left pocket flap.

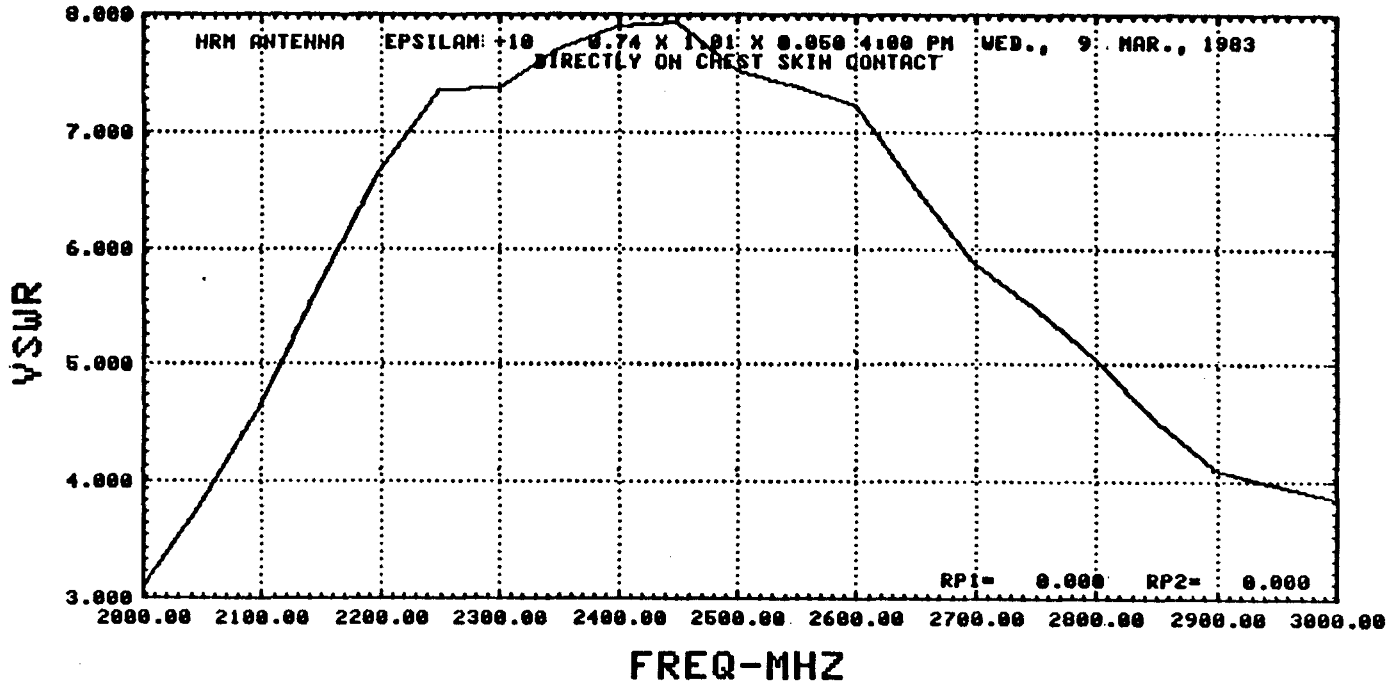


Figure C-8. VSWR plot, beam from patch antenna directed into chest with antenna in contact with skin.

APPENDIX D

BALANCED MIXER POSITIONAL DEPENDENCY TEST

As mentioned in the text of this report, positional dependency was a problem when simple mixing techniques were used for the cw microwave radar sensitivity and frequency comparison tests. A balanced mixer consisting of two Schottky mixer diodes and a ring hybrid, which offsets the two diodes by 90° in phase, was designed for the Noninvasive Heart Rate Monitor. Prior to integrating the balanced mixer into the monitor, a test was performed to demonstrate that null readings would not occur at any spacing between the antenna and the target.

The test arrangement shown in Figure D-1 was used. A small dielectric shaft was set up under the antenna and the microwave system which had been mounted on a moveable lab jack. Since the shaft was reasonably uniform, there was no relative motion and no Doppler signal was generated. A small strip of metal tape was positioned on the shaft at one point to provide a moving target as the shaft was slowly rotated by a low RPM gearmotor.

The voltage output of each mixer diode was observed separately and as a summed signal on a storage oscilloscope at several positions as the antenna was elevated away from the rotating shaft. The oscillograph waveforms were protographed and are attached as Figures D-2 through D-10.

As the spacing increases, the signal decreases as expected and this is not a cause for concern. The problem is that the amplitude of either mixer signal can go through a null, as shown by Mixer 1 at Step 4 where the signal is noticeably smaller than for either Step 3 or 5. The same tendency to go through a null is shown by Mixer 2 at Step 7. The effect would be more pronounced if the target motion were small and the step increments were finer. By summing the two mixer voltages, some signal will be available at any spacing, thereby removing much of the positional dependency of the cw microwave radar design approach.

BALANCED MIXER

POSITIONAL SENSITIVITY TEST

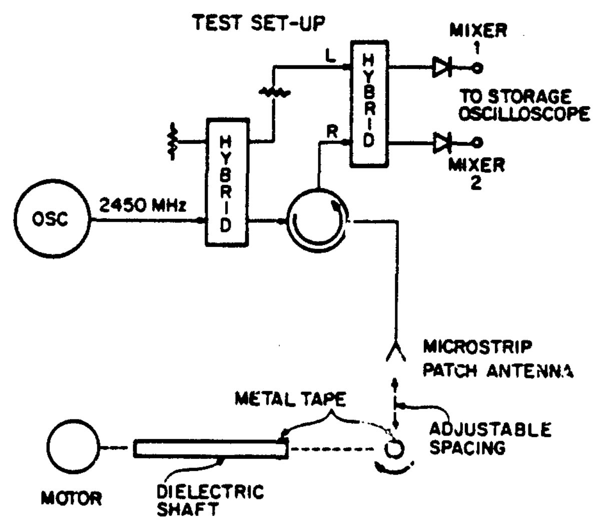


Figure D-1

STEP No. 1
RELATIVE POSITION 25 mm

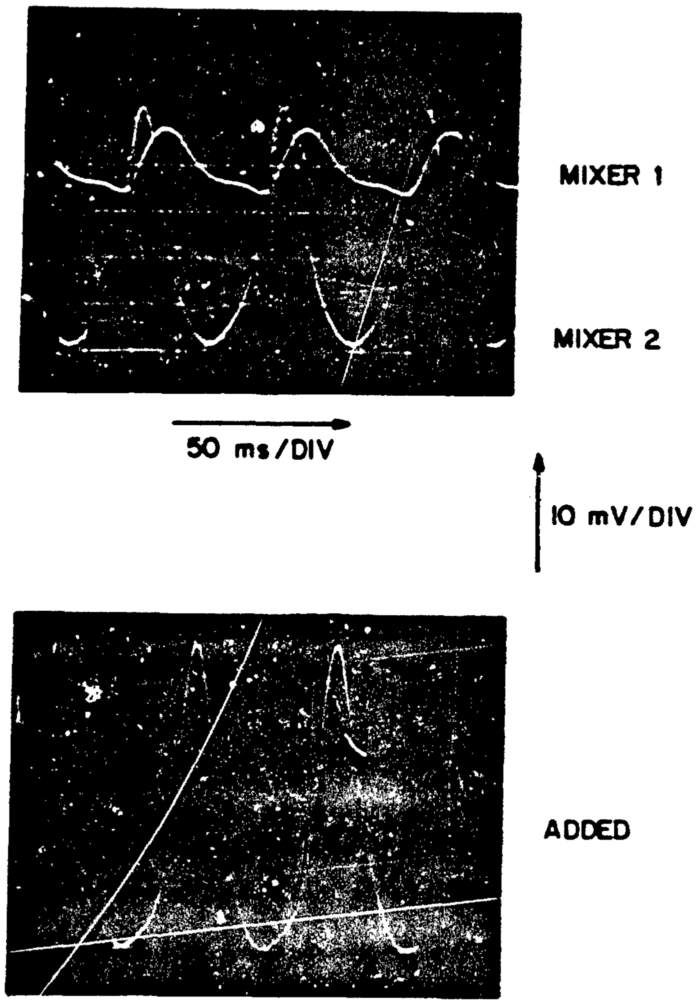


Figure D-2.

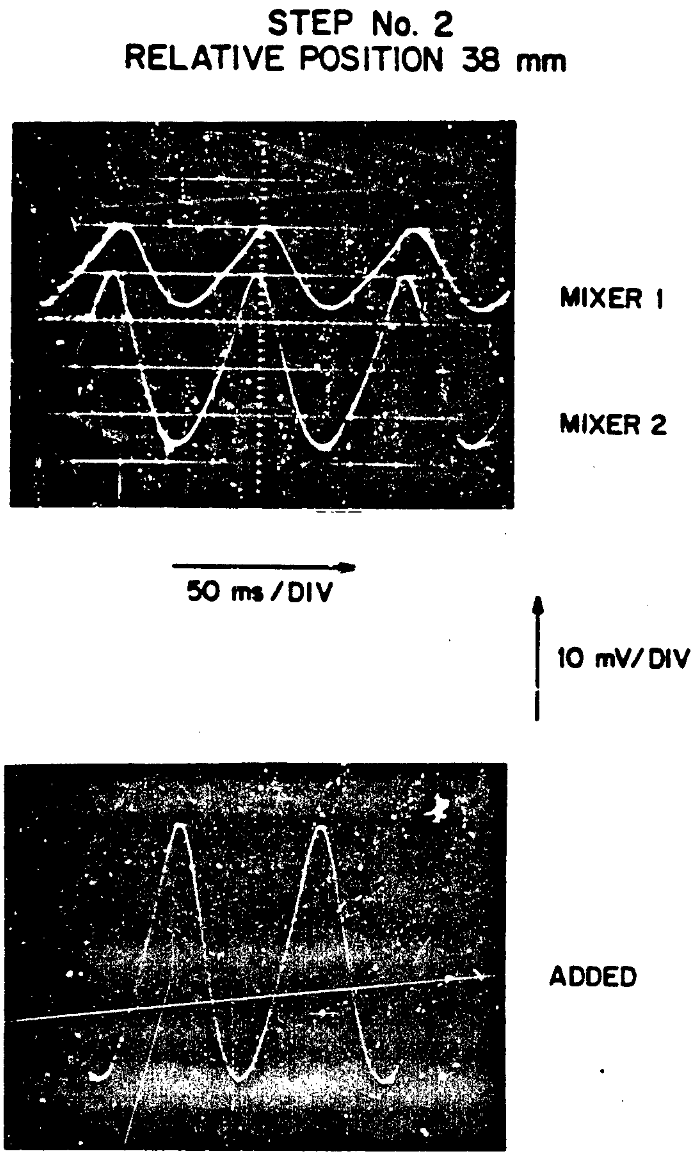

STEP No. 2
RELATIVE POSITION 38 mm
MIXER 1
MIXER 2
50 ms / DIV
10 mV/ DIV
ADDED

Figure D-3.

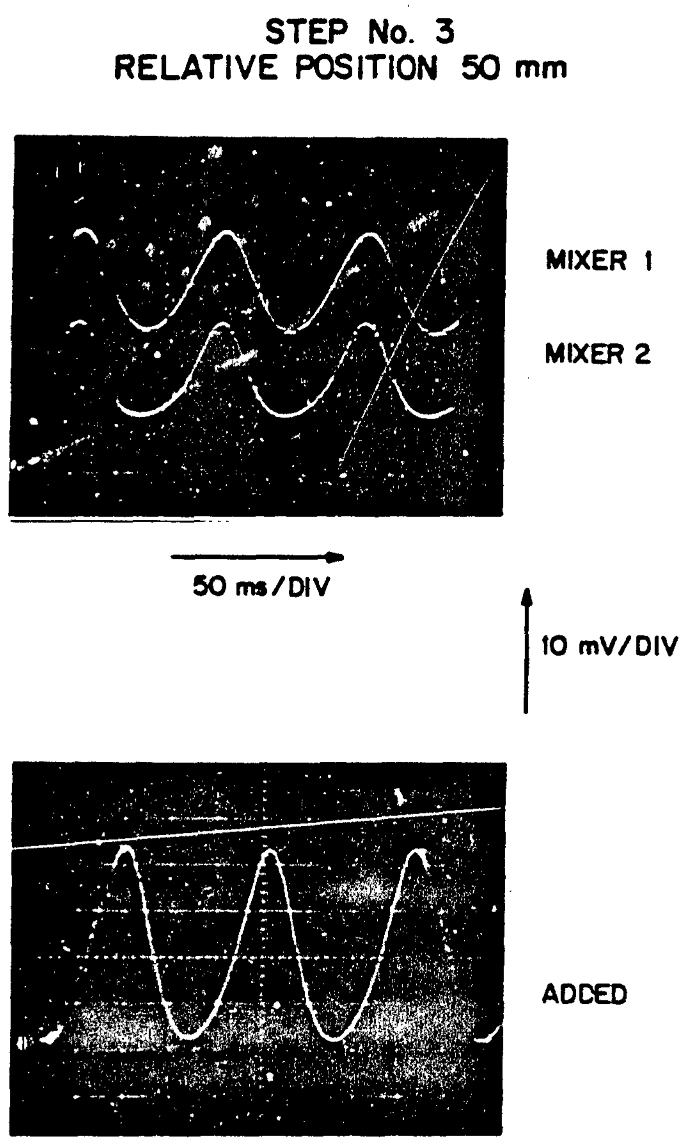

STEP No. 3
RELATIVE POSITION 50 mm
MIXER 1
MIXER 2
50 ms/DIV
10 mV/DIV
ADDED

Figure D-4.

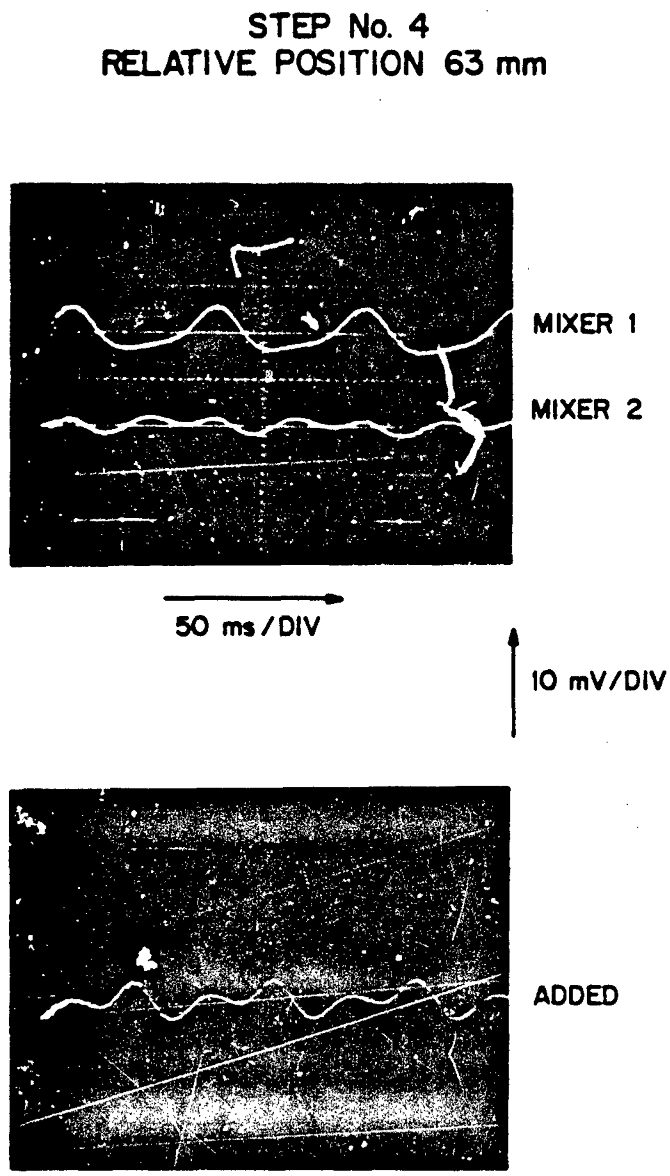

STEP No. 4
RELATIVE POSITION 63 mm
MIXER 1
MIXER 2
50 ms / DIV
10 mV/DIV
ADDED

Figure D-5.

STEP No. 5
RELATIVE POSITION 75 mm

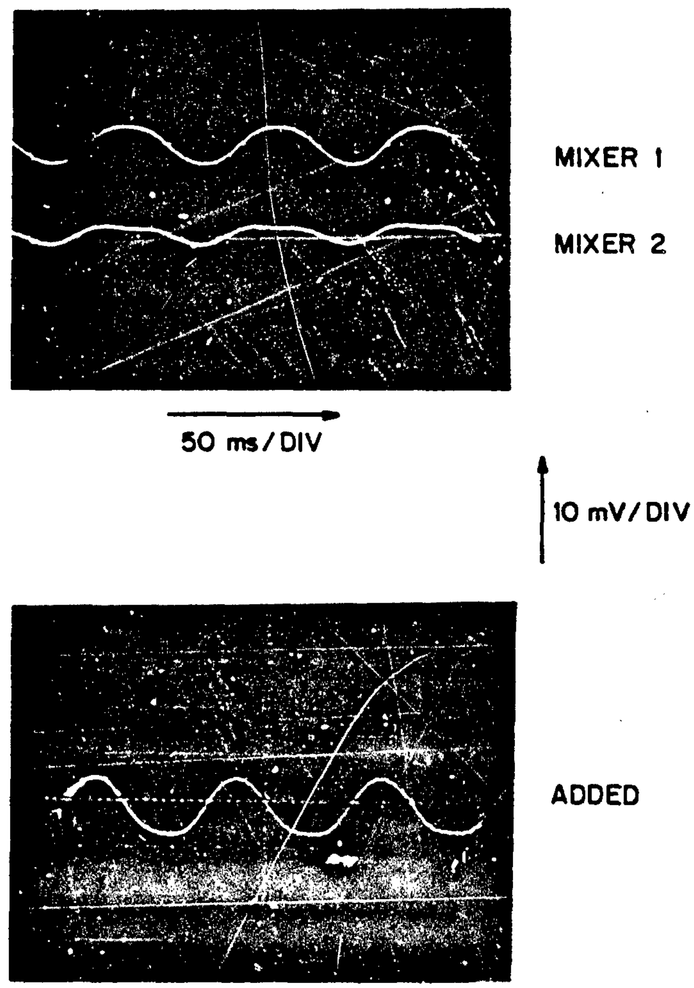


Figure D-6.

STEP No. 6
RELATIVE POSITION 88 mm

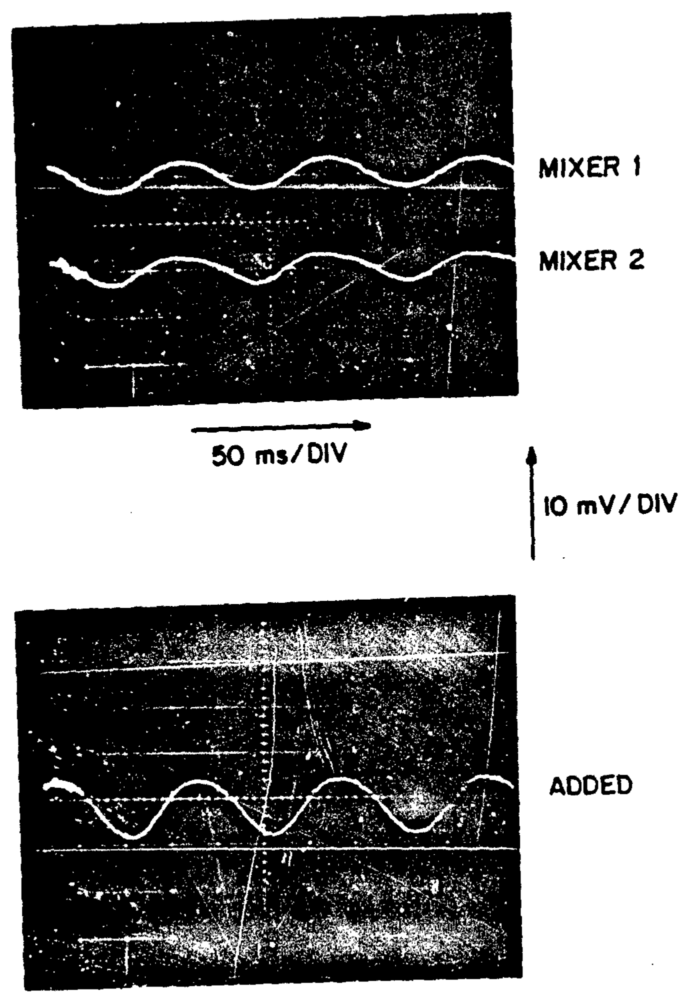


Figure D-7.

STEP No. 7
RELATIVE POSITION 100 mm

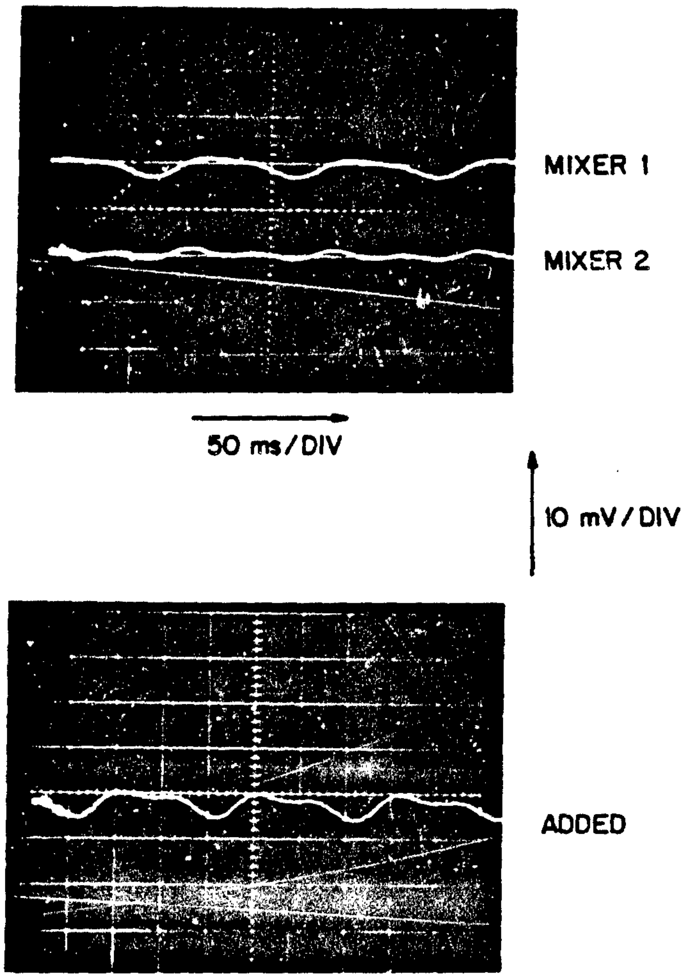


Figure D-8.

STEP No. 8

RELATIVE POSITION 112 mm

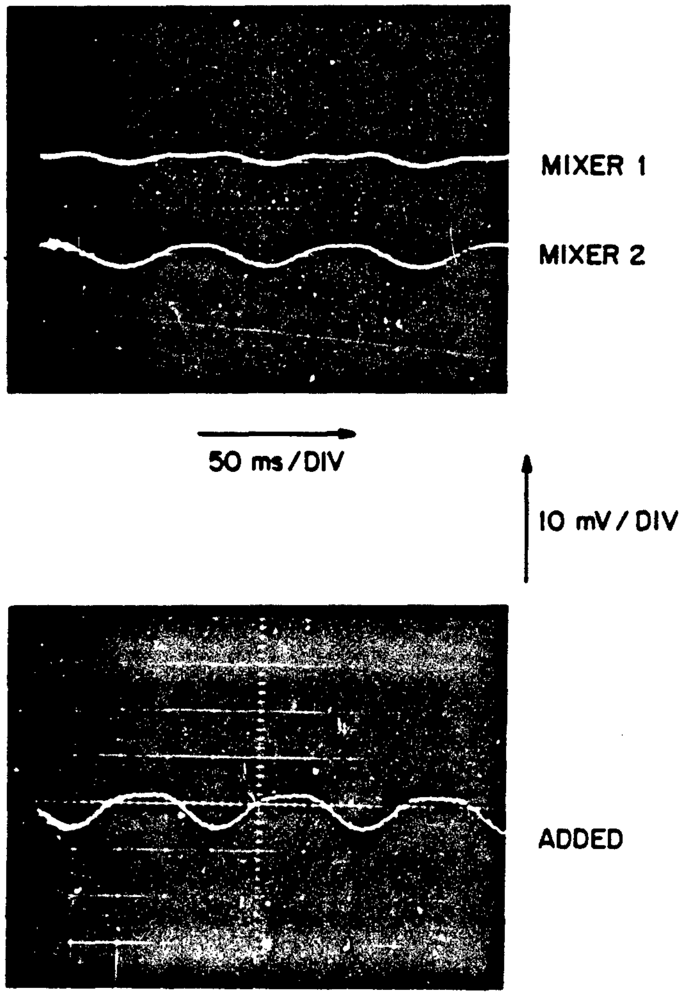


Figure D-9.

STEP No. 9
RELATIVE POSITION 125 mm

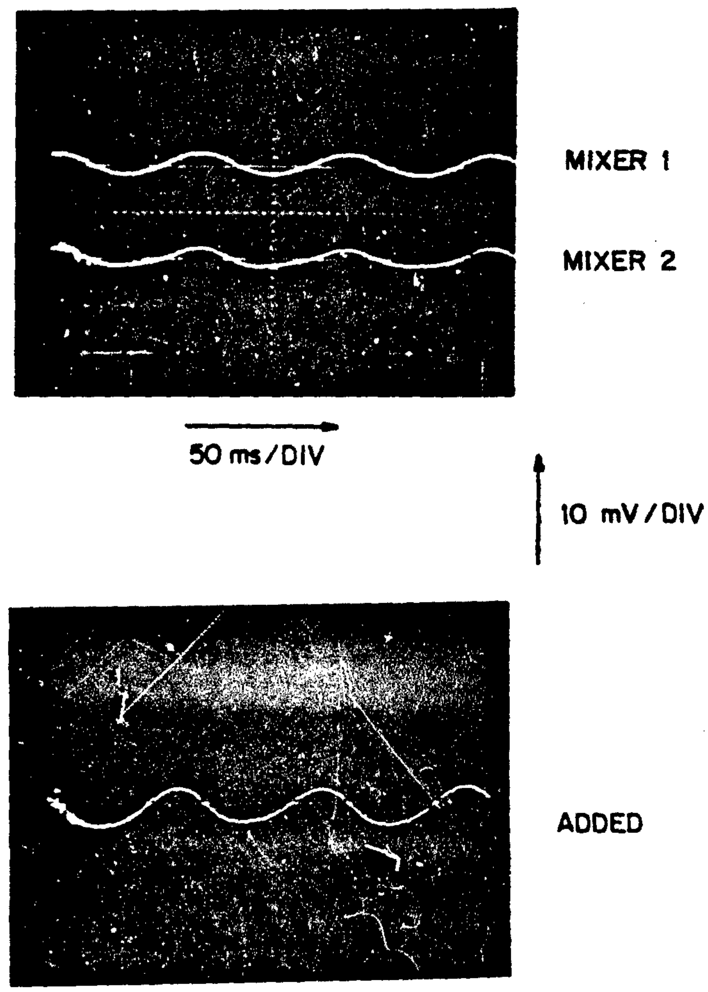


Figure D-10.

APPENDIX E

RADAR SENSITIVITY MEASUREMENTS

Using the test setup in Fig. E-1a, various combinations of available microwave components were assembled as cw microwave radar systems to perform sensitivity measurements as a function of requency and relative position of the antenna and test subject.

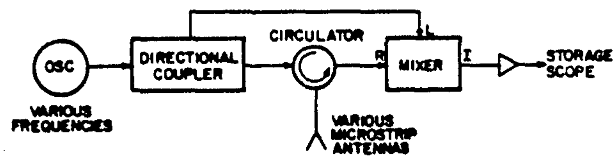
Mixer output waveforms under the various conditions were recorded on a storage oscilloscope and the photographs are attached as Figures E-2 through E-16. The waveforms in Figure E-2 were taken with the 2 Ghz antenna pressed against the chests of two different subjects without the table and other apparatus. All the other waveforms were taken on a single subject, wearing the supplied combat coat marked with a locating grid, lying on the table as indicated in Figure E-1b.

More distinct waveforms were obtained when the antenna was held against the chest than when the subject and the antenna were separately supported by the table and cart, but reference locations could not be maintained without such an arrangment. In retrospect, testings with the radar mounted remote from the subject, even when in contact, was not a good approach because there were many sources of relative motion and vibration that introduced extraneous signals; however it did serve to emphasize the need for direct contact of the monitor on the patient in the field.

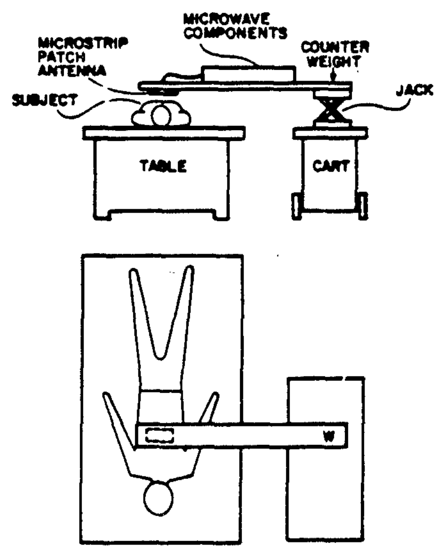
The various photographs are marked with the condition of the specific test being performed. After reviewing the waveforms, the following general conclusions were drawn:

1. There is more positional sensitivity at the higher frequencies which should be expected since the wavelengths are shorter and interference patterns will occur more closely.
2. Heavy wall pressure causes smaller signals, probably because chest wall motion is suppressed.
3. The waveforms are complex and vary widely, indicating that the signal results from the composite of several different motions.
4. Mapping measurements at 8 GHz show variations in signal, but usable signals are present over a wide area.
5. The signal processor must be able to handle a wide range of amplitude and waveform variations.

TEST SET-UP FOR SENSITIVITY MEASUREMENTS



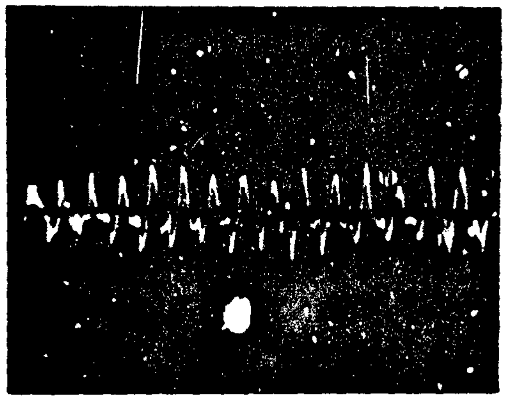
(a)



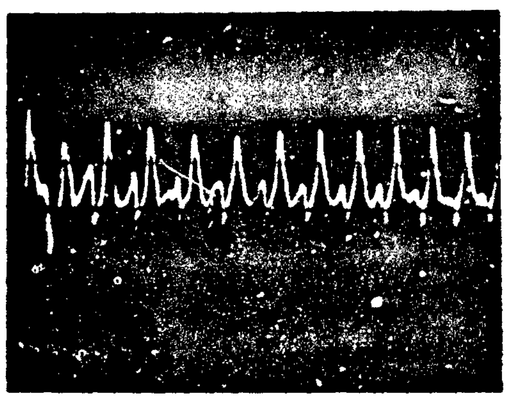
(b)

Figure E-1.

2- GHz PATCH ANTENNA AT
2150 MHz



HELD AGAINST
CHEST OF
SUBJECT DM



HELD AGAINST
CHEST OF
SUBJECT HM

1.0 sec / DIV

Figure E-2.

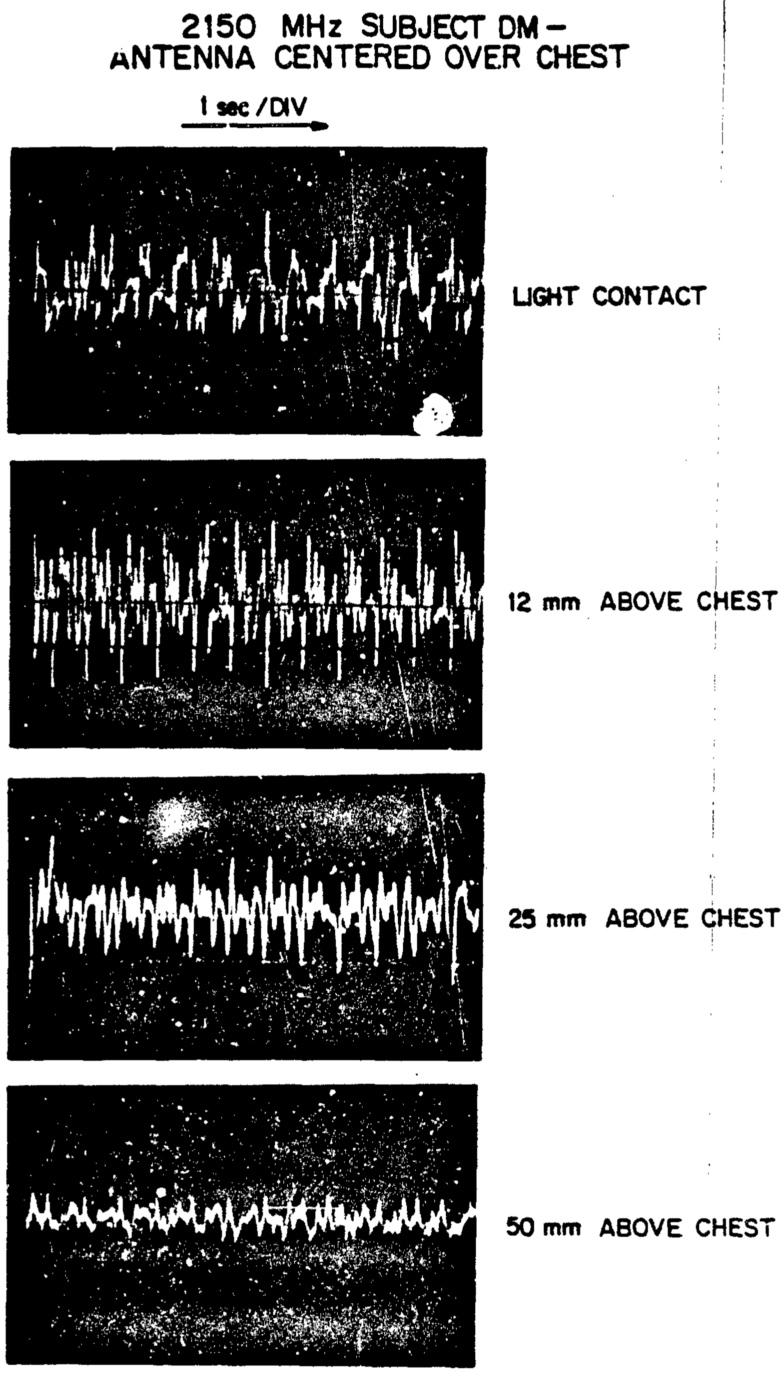
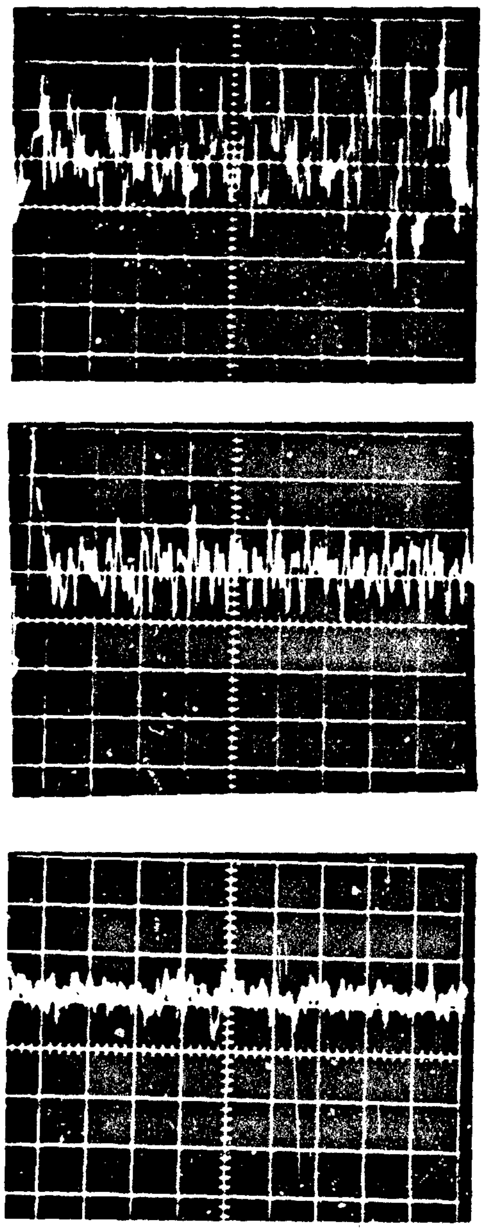

2150 MHz SUBJECT DM -
ANTENNA CENTERED OVER CHEST
1 sec /DIV
LIGHT CONTACT
12 mm ABOVE CHEST
25 mm ABOVE CHEST
50 mm ABOVE CHEST

Figure E-3.

2150 MHz SUBJECT DM —
ANTENNA 25 mm LEFT OF CENTER



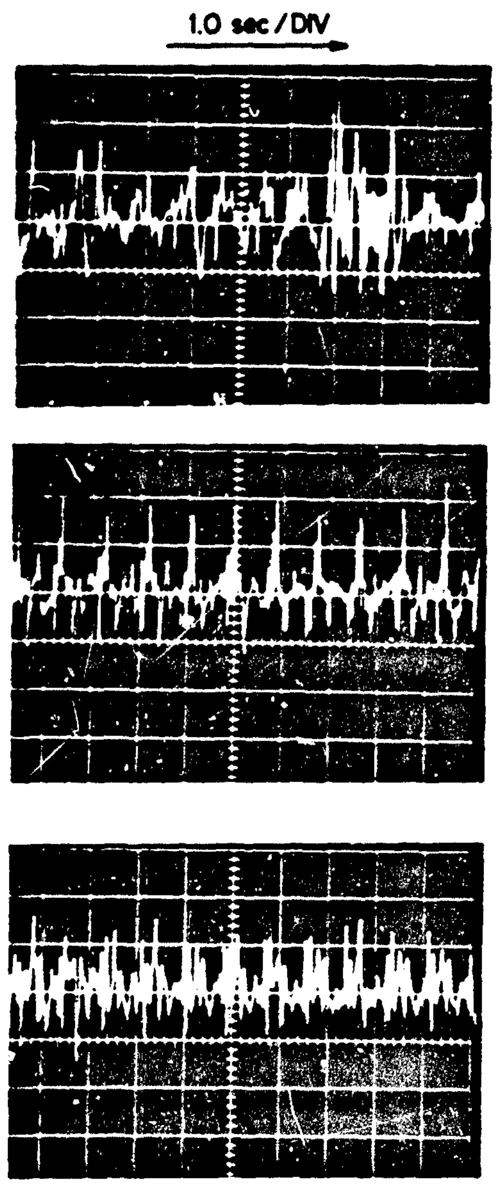
LIGHT CONTACT

12 mm ABOVE CHEST

25 mm ABOVE CHEST

Figure E-4.

2150 MHz SUBJECT DM-
ANTENNA 50 mm LEFT OF CENTER



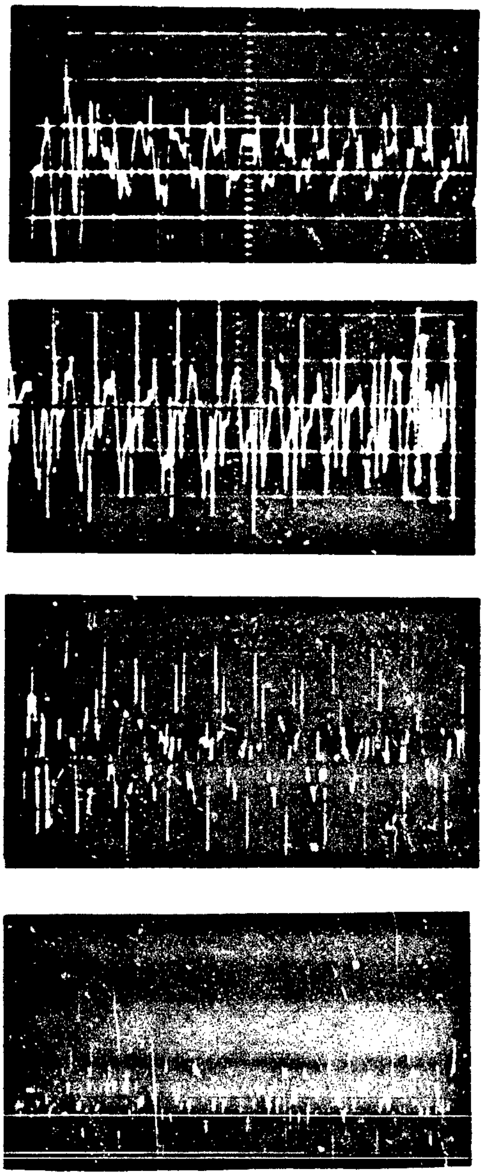
LIGHT CONTACT

12 mm ABOVE CHEST

25 mm ABOVE CHEST

Figure E-5.

2150 MHz
TEST SET MOVED AWAY FROM INTERFERENCE
SUBJECT DM - ANTENNA 25 mm LEFT OF CENTER



MODERATE PRESSURE

LIGHT PRESSURE

CONTACT NO PRESSURE

12 mm ABOVE CHEST

Figure E-6.

4200 MHz
SUBJECT DM-CENTERED ON CHEST

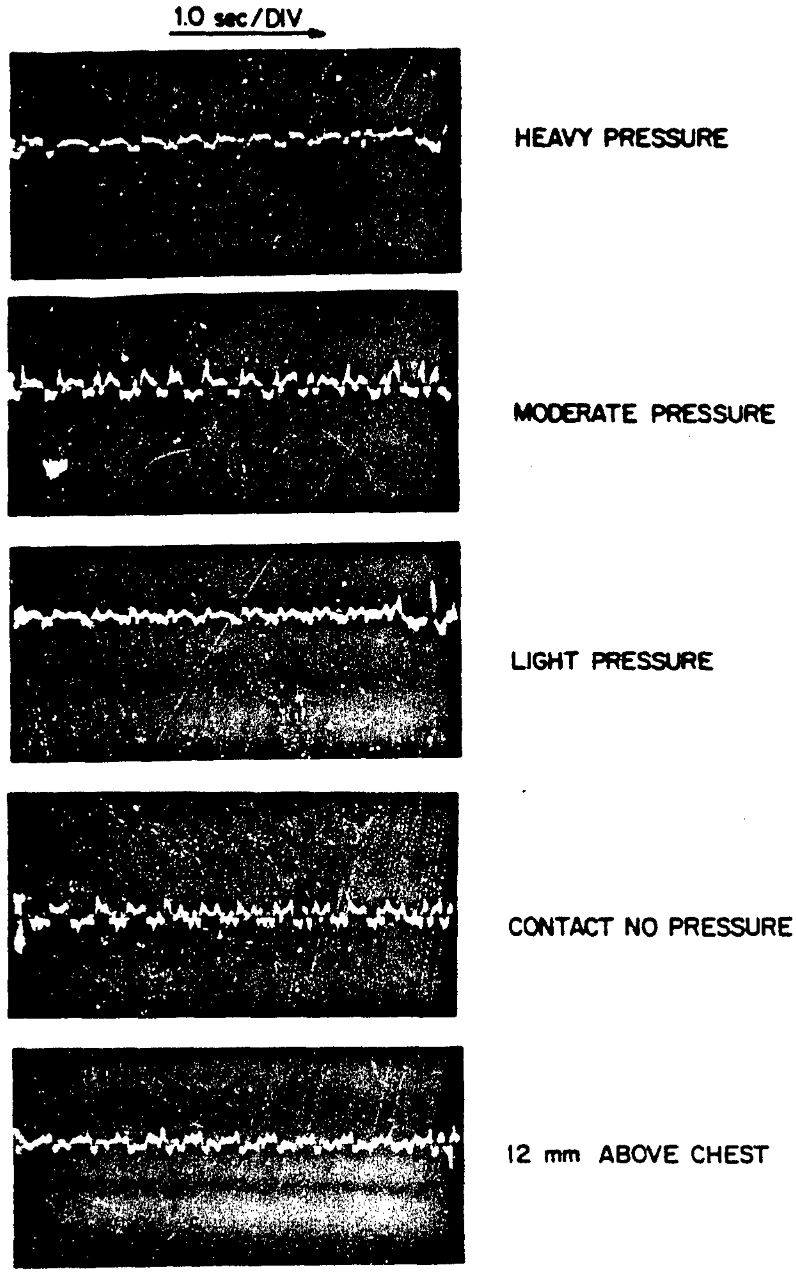


Figure E-7.

6400 MHz SUBJECT DM-
CENTERED OVER STERNUM

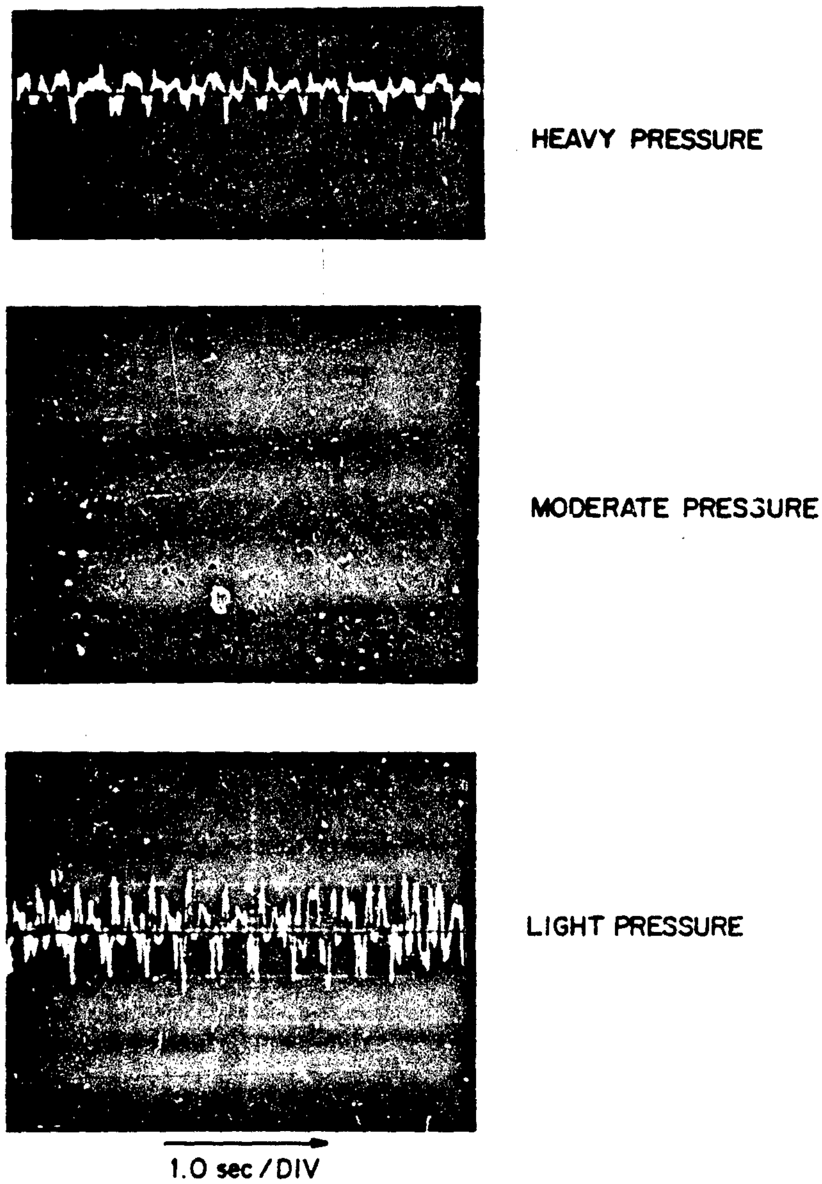
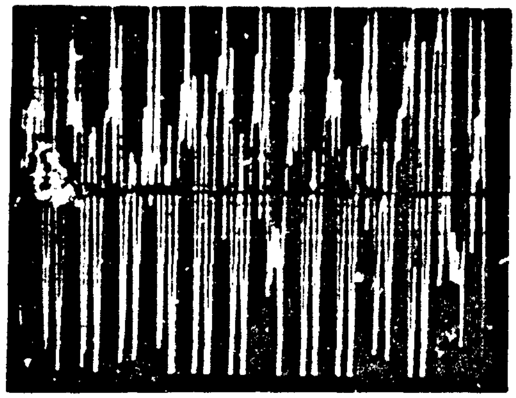


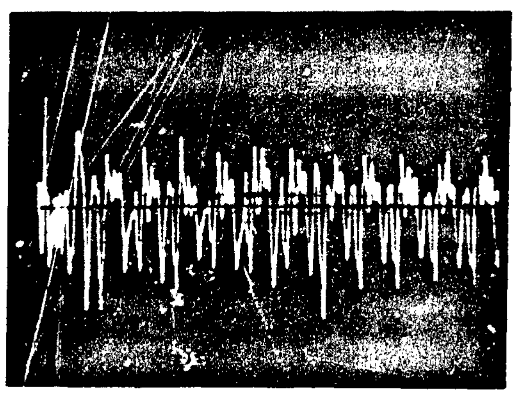
Figure E-8.

6400 MHz (CONT.)

1.0 sec/DIV



CONTACT NO PRESSURE

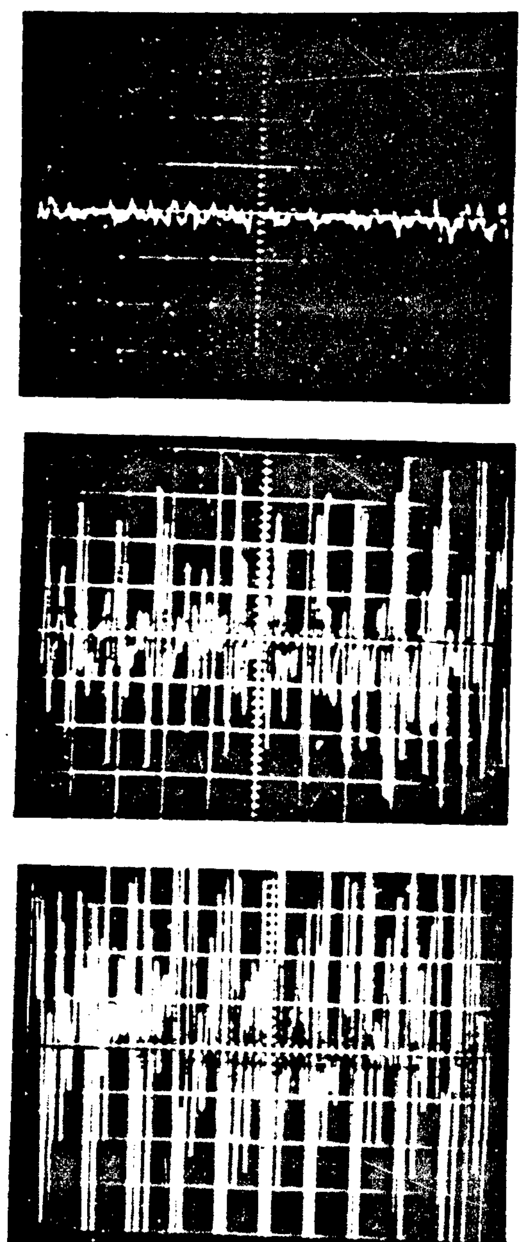


12 mm ABOVE CHEST

Figure E-9.

8000 MHz
SUBJECT DM-CENTERED ON CHEST

1.0 sec/DIV



HEAVY PRESSURE

LIGHT PRESSURE

12 mm ABOVE CHEST

Figure E-10.

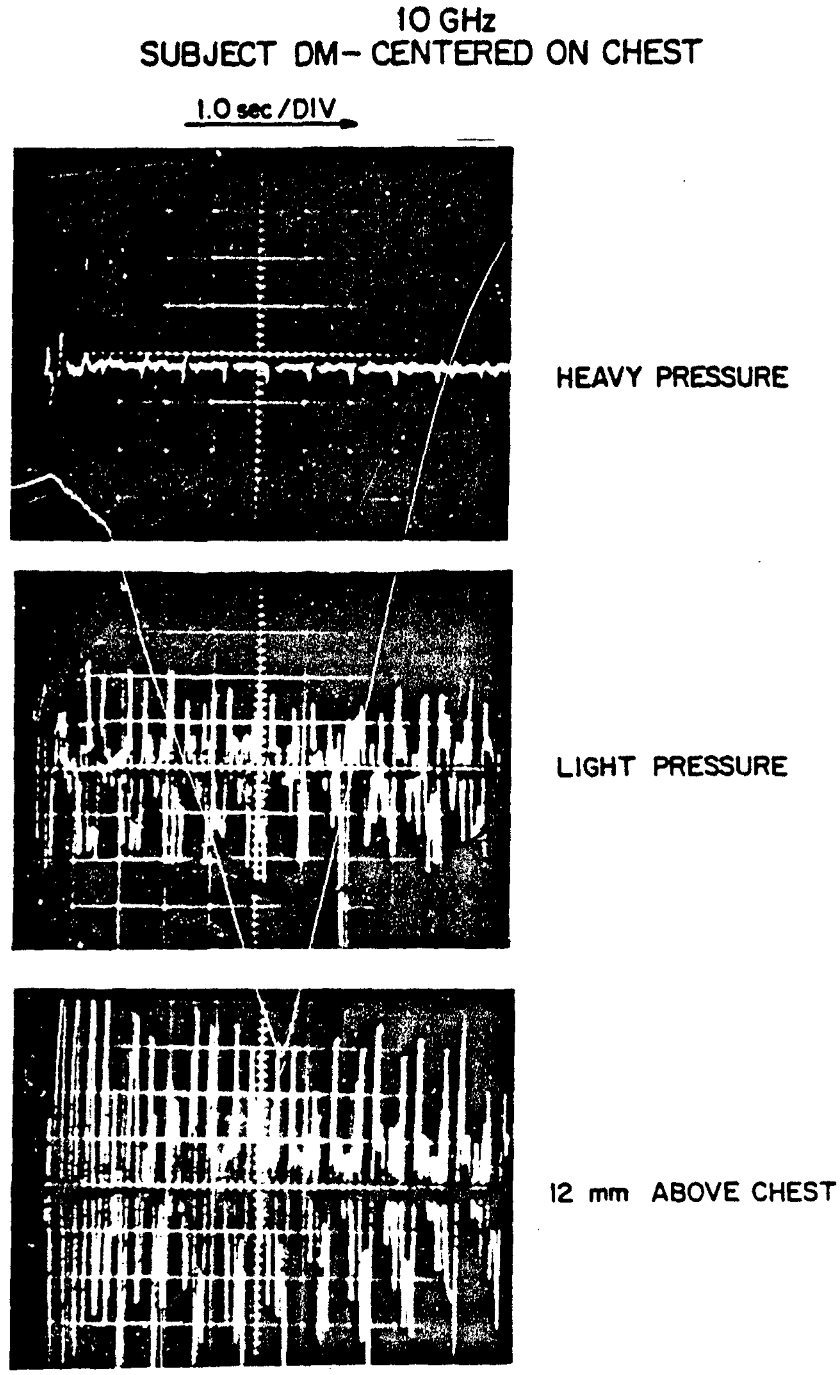

10 GHz
SUBJECT DM- CENTERED ON CHEST
1.0 sec/DIV
HEAVY PRESSURE
LIGHT PRESSURE
12 mm ABOVE CHEST

Figure E-11.

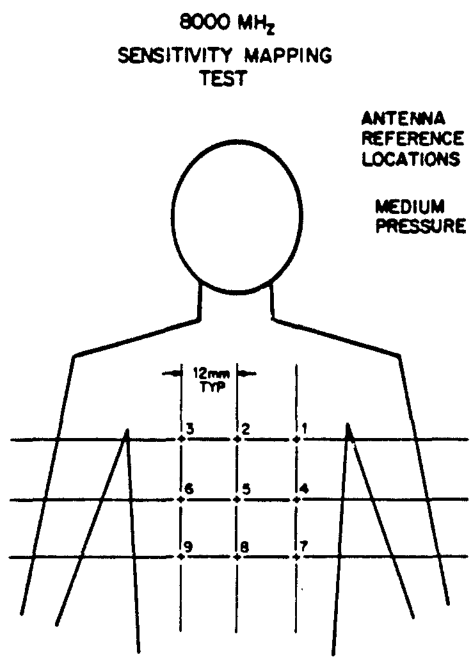
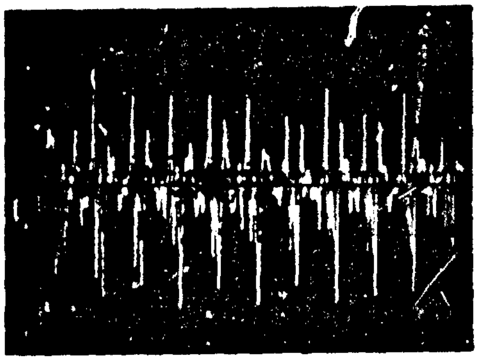

8000 MHz
SENSITIVITY MAPPING TEST
ANTENNA REFERENCE LOCATIONS
MEDIUM PRESSURE
12mm TYP
3
2
1
6
5
4
9
8
7

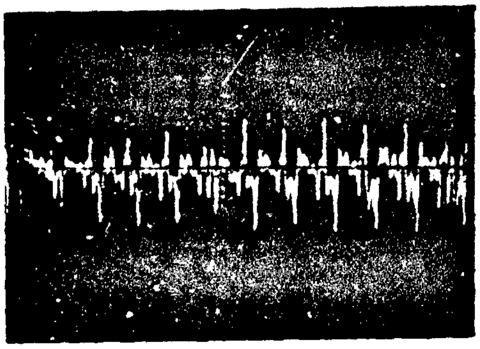
Figure E-12.

8000 MHz MAPPING TEST
SUBJECT DM - VARIOUS LOCATIONS RELATIVE TO STERNUM

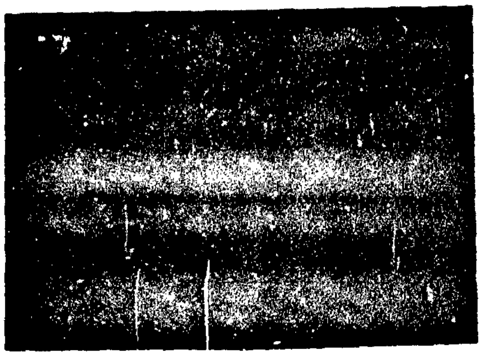
1.0 sec/DIV



POSITION 2
TOP CENTER



POSITION 5
CENTER

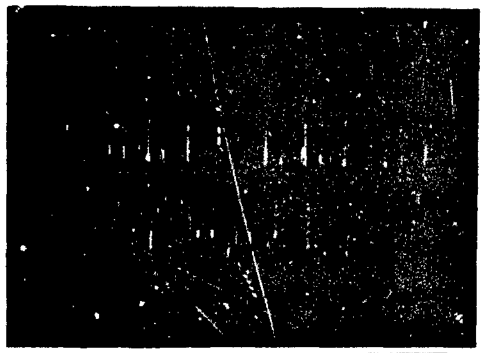


POSITION 8
BOTTOM CENTER

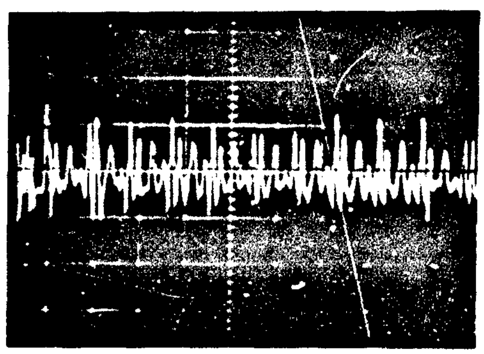
Figure E-13.

8000 MHz MAPPING TEST

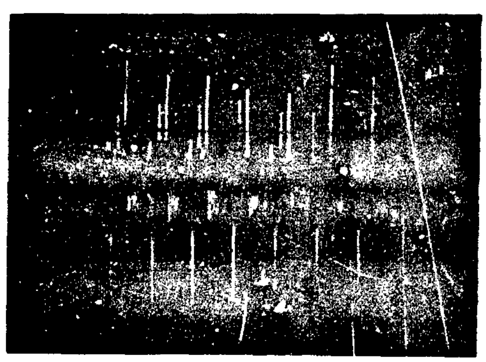
1.0 sec/DIV



POSITION 3
TOP RIGHT



POSITION 6
CENTER RIGHT

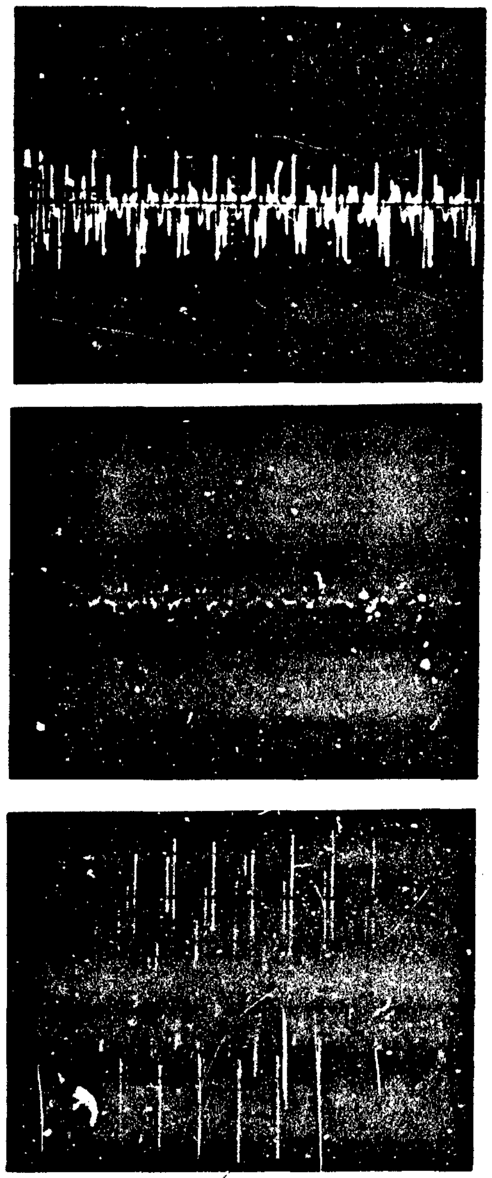


POSITION 9
BOTTOM RIGHT

Figure E-14.

8000 MHz MAPPING TEST

1.0 sec / DIV



POSITION 1
TOP LEFT

POSITION 4
CENTER LEFT

POSITION 7
BOTTOM LEFT

Figure E-15.

APPENDIX F

FDA COMPLIANCE

This appendix presents a copy of RCA's application for investigational device exemption, submitted to the U.S. Food and Drug Adminstration, Bureau of Medical Devices on April 26, 1983.

April 26, 1983

Joseph L. Hackett
Bureau of Medical Devices, HFK-403
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

RCA

Dear Mr. Hackett:

Under Contract No. DAMD17-83-C-3018 with the U.S. Army Medical Research and Development Command, RCA Laboratories is developing a noninvasive heart rate monitor to be used with chemical protective overgarments. Inasmuch as human subjects may be used in testing the monitor, we wish to be in compliance with 21 CFR, Part 812 Investigational Device Exemption (IDE) Regulation.

We do not have an Institutional Review Board (IRB) at RCA Laboratories and are unaware of the existence of an IRB in the immediate area. We are, therefore, submitting the following description of the proposed device and respectfully requesting your concurrence with our opinion that it does not represent a significant risk device.

As presently envisaged, our device will be approximately the size of a package of cigarettes and will have a flat, printed-circuit antenna on one face (the face which will be placed against the chest of a subject wearing protective clothing, - not near the eyes or any other heat-sensitive part of the body) and a digital readout on the opposite face. Movements of the chest wall cause reflections of a weak microwave signal emitted by the antenna to contain components of the heartbeat rate which are converted by signal-processing circuitry into a signal suitable for activating a digital heart rate readout. Upon activation for a particular measurement, the device will average readings over not more than a 60-second time interval, then shut itself off.

The frequency of operation of the device is 2.45 GHz and the transmitted power is 10 mW. The metalized "patch" of the antenna has dimensions of 1.83 cm x 2.54 cm (.72" x 1.0"), so that its area is 4.65 cm^2. In the worst case, i.e. if we assume no beam spreading between the antenna and the body of the subject, the power density during the measurement will therefore be 10 mW / 4.65 cm^2 = 2.15 mW/cm^2 (the attenuation suffered by the signal in penetrating the protective clothing is negligible).

My direct Dial Number is (609)-734 2712

Mr. Joseph L. Hackett
Page 2
April 26, 1983

The ANSI C95.1-1982 radio frequency protection guide for whole body exposure of human beings at a frequency of 2.45 GHz permits a maximum exposure of 5 mW/sq cm. Considering that the maximum exposure, as calculated above, for a total of a few 60-second intervals only, on a limited area of the chest is less than one-half that permitted by the ANSI standard for whole-body exposure, we conclude that the instrument is not a significant risk device within the meaning of 21 CFR 812, and we request permission to perform preliminary experiments on personnel for the purpose of refining the design and for packaging a prototype demonstration-model instrument as required by our contract.

Please notify us immediately if you require any additional information in connection with this request.

Very truly yours,

Russell B. Chase
Manager, Contracts

ajq

cc: Patricia M. McAllister
USAMRDC